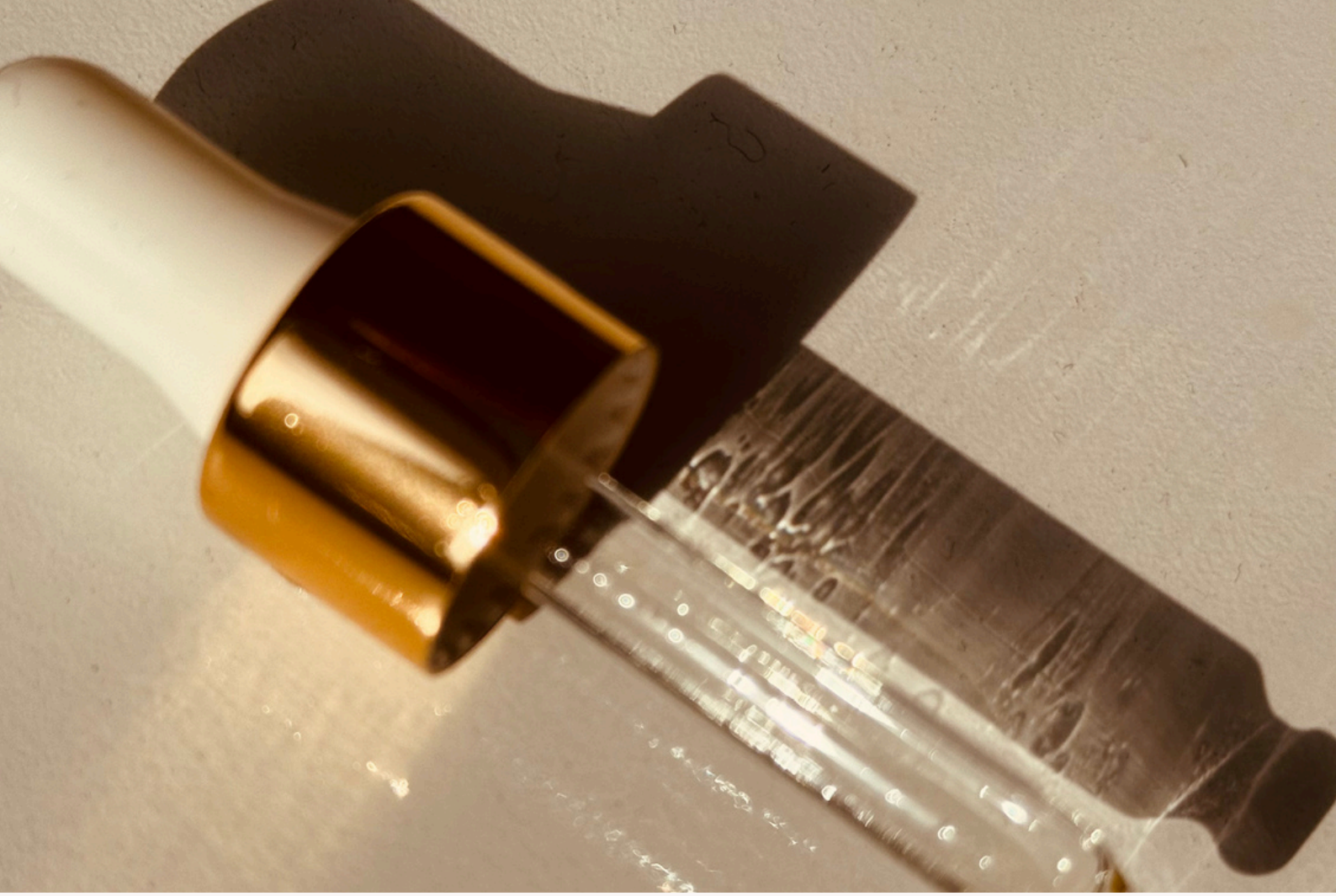

Labelling Requirements for Cosmetic Products

A plug-and-play checklist to turn *your* artwork into a compliant label

by Dr Paula Walencik
Cosmetic Chemist & Regulatory Affairs Specialist

Part 2
Packaging Set
(outer & inner packaging)

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Dr Paula Walencik - The Go-To Platform for Cosmetics Regulatory Affairs



an extremely long but totally worth reading foreword

What pushed me to create this rulebook?

I know exactly what beauty founders run into when they start creating the artworks for their products.

I made regulatory reviews for more than 190 cosmetic items, and I can tell you one thing with full confidence: every single one had some sort of labeling issue. Sometimes it was the formula details, other times, it was about inconsistencies around the PAO or inappropriate claims.

But… is a cosmetic label actually THAT important?

We tend to think of labels as a small, marketing-ish detail. And that's quite understandable, especially when you think about how much time and effort are needed for other parts of NPD like formulation work, testing, and marketing campaigns.

But the truth is, cosmetic labels have to follow strict regulations. Just like it happens in the pharma and food sectors. And that means that every cosmetic label has to meet specific requirements and include certain mandatory information.

So I hope you now get my point that cosmetic labels aren't just about branding, marketing, or looking pretty on a shelf. They're fully regulated, with clear rules you have to follow. You can't just slap on whatever looks good or appeals to your target audience.

That`s the part where marketing and compliance need to work together.

But no need to stress, I'm here to make this thing easier for you.

Like I said earlier, Regulation 1223/2009 sets out the basic rules for cosmetics labels. Knowing these requirements is the bare minimum, and that's exactly why I put together this rulebook for you.

This particular file is designed for regular-sized products with a packaging set (like jar + box or tube + box). However, on my platform Urban Beauty Brand, you'll also find guides made for products with single packages, and for small-sized products under 5 ml or 5 g.

So, first things first, make sure you're using the right guide.

Each rulebook is broken down into sections based on the type of information it covers. For example, there's "Main Editorial Requirements," "Responsible Person (RP) Information," "Function of the Product," "Precautions and Warnings," and so on.

On top of that, each file includes a bonus: my personal comments and notes. They highlight exactly what to look for and point you to where in the Product Information File you can find the data needed to create a flawless label.

Will this rulebook let me complete my cosmetic label 100%?

It will definitely guide you through the core requirements of Regulation 1223/2009. But as I mentioned earlier, every product and every label is unique, and some things need to be handled on a case-by-case basis.

Beyond Regulation 1223/2009, you also have to consider Regulation 655/2013, which means looking at your marketing claims individually. Then there's also eco-labelling, which means reviewing your packaging and thinking about whether you plan to sell in EU countries with local rules.

This workbook can be your roadmap for getting started or double-checking your artwork. But if you're looking for more tailored guidance or deeper insights, I invite you to explore my other materials on the Urban Beauty Brand platform or reach out directly for personalized support.

And if you`re ready to dive in?

Let's start and make your label compliance easy and stress-free!

how a bored scientist turned into a beauty nerd...

Okay, let`s be honest! “About me” sections are usually boring and skipped by everyone. And that`s a big mistake!

Why? Because learning about the experience and expertise of the person guiding you is always a smart move. Don`t you think?
So, please take a moment, relax, and let me share a bit about who I am.

I promise to keep it shorter than the forward part ;)

A few years back, I wrapped up my PhD in chemistry, and I spent several years working in different research centers, diving into projects, planning experiments, taking chemicals all the way to the preclinical stage, and managing cell labs.

DR PAULA WALENCIK
COSMETIC CHEMIST & REGULATORY AFFAIRS SPECIALIST

But somewhere along the way, I realized I wanted to take my science in a more creative direction. That’s when I decided to switch gears, start studying cosmetics NPD, and step into the beauty space.

I’d already built a great career, but that wasn`t enough. I decided to hit pause and try something new. And that’s pretty much how my journey in Cosmetics Regulatory Affairs began.

I started out doing regulatory reviews for RP offices in London and Warsaw. Then a few cosmetic brands noticed my work and began reaching out for direct support.

But the longer I worked in Cosmetics Regulatory Affairs, the more I saw how many challenges beauty founders deal with. Every day, my messages and calls were around the same problems:

"You have an ingredient that's banned in the EU - you'll need to reformulate."
"You're missing compatibility testing; that needs to be added."
"Your PIF is incomplete, you're missing x, y, and z."
"You can't use this claim; it goes beyond the definition of a cosmetic product."
"How did you figure out the PAO?"
"Your label is incomplete."
"Those ingredients don't match your QQ file."
"Why didn't you list all the allergens?"
"Looks like the fragrance documentation is missing a few pieces."
"Your label is missing the warnings from Safety Assessor."

No jokes... this was and actually still is my daily reality.

And telling managers and beauty founders all this is never exactly fun. Because people don't usually love hearing when there's a problem with their product, or when something needs fixing before it can even hit the shelves.

And I get it 100%! Because every hour spent fixing mistakes is money going out, not coming in.

So I decided to do something about it. Since I was already explaining to some beauty founders what was wrong with their products, I figured out that I could share that more widely and help people see just how important Cosmetics Regulatory Affairs is for their business.

I started noting every error I spotted in ingredients, labels, and docs, and began turning those thoughts into LinkedIn posts. Over time, this evolved into my platform, Urban Beauty Brand, and then into the workbook you are currently reading.

And if there's one thing I've learned from working on over 190 cosmetic products, it's that every product is a long-term project and a reflection of your brand and the values behind it. **Sure, manufacturers will tempt you with template formulas and promises of launching a product in less than three months. But if you really want your brand and your products to stand out, it's worth putting in a bit more care, effort, and attention during the design process.**

And I hope this guide will make that journey a bit easier for you.

LET'S MAKE *YOUR* COSMETIC VISION A REALITY – POLISHED, COMPLIANT, AND *LAUNCH-READY FOR THE EU & UK*


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Dr Paula Walencik - The Go-To Platform for Cosmetics Regulatory Affairs

Regular-Sized (≥5 g or ≥5 ml) Packaging Set including Outer and Inner Packaging

(i.e. Primary & Secondary Packaging or Container & Packaging)

Requirements for outer packaging

01 Main Editorial Requirements

All label text and elements are clear, easy to read, and non-erasable.

02 Responsible Person (RP) Information

Name or Registered Name of the Responsible Person (RP) is provided.

Address of the RP is listed and clearly identified.

If multiple addresses are provided, highlight the relevant address for RP.

Abbreviations used must allow identification of RP and its address.

03 Product Function

Function of the product is indicated (unless self-explanatory).

Written in the language required by the laws of the Member State where the product will be sold.

04 Precautions and Warnings

Warnings regarding use are listed (especially for professional use products).

All warnings recommended by the Safety Assessor are also included (check the "Labeling & Warnings" panel in Part B of CPSR).

Include any required warnings from Annexes III to VI (applies to specific ingredients).

Warnings are written in the language required by the laws of the Member State where the product will be sold.

05 Batch/Lot Number

Batch, Lot number, or any reference number that enables recognition of the production series is provided.

06 Country of Origin

The phrase “Made in …” is included. This applies to cosmetic products imported into the EU/UK or produced outside the EU/UK.

07 Ingredients List

Preceded by the word “Ingredients:”.

All ingredients listed using INCI nomenclature (verify the names using CoSing database).

The list follows the correct order based on the QQ file and includes all ingredients and allergens.

08 Expiry Date

Expiry date is indicated for products with a durability of under 30 months.

Expiry date is marked with the “hourglass” symbol or the phrase “best used before the end of…”.

“best used before the end of…” is written in the language required by the laws of the Member State where the product will be sold.

Expiry date format: Month/Year (MMYY or MMYYYY) or Day/Month/Year (DDMMYYYY or DDMMYY).

Not mandatory for products with durability over 30 months.

Not mandatory for products from the "low-microbiological risk" group (check ISO 29621:2017-04 guidelines).

If durability requires special storage/usage conditions, this information is included.

09 Period After Opening (PAO)

PAO is indicated for products with durability over 30 months.

PAO is designated by the “open jar” symbol followed by the period in months or years (e.g., 6M, 2Y).

PAO is consistent with test results (check stability & compatibility results and CPSR stability section).

PAO is allowed but not mandatory for products with a durability of under 30 months.

Not mandatory for products from the "low-microbiological risk" group (check ISO 29621:2017-04 guidelines).

10 Nominal Content

Nominal content is listed by weight (grams [g], kilograms [kg]) or volume (milliliters [ml], liters [l]).

Units are written in correct SI format (e.g., 10 g, 10 ml).

Font size is correct:

- **2 mm for packaging < 50 g or 50 ml**
- **3 mm for packaging between 50 g-200 g or 50 ml-200 ml**
- **4 mm for packaging between 200 g-1 kg or 200 ml-1 l**
- **5 mm for packaging > 1 kg or 1 l**

11 The Open Book Symbol

The Open Book Symbol is included if any label information is provided on an enclosed or attached leaflet, label, tape, tag, or card.

Requirements for inner packaging

01 Main Editorial Requirements

All label text and elements are clear, easy to read, and non-erasable.

02 Responsible Person (RP) Information

Name or Registered Name of the Responsible Person (RP) is provided.

Address of the RP is listed and clearly identified.

If multiple addresses are provided, highlight the relevant address for RP.

Abbreviations used must allow identification of RP and its address.

03 Product Function

Function of the product is indicated (unless self-explanatory).

Written in the language required by the laws of the Member State where the product will be sold.

04 Precautions and Warnings

Warnings regarding use are listed (especially for professional use products).

All warnings recommended by the Safety Assessor are also included (check the “Labeling & Warnings” panel in Part B of CPSR).

Include any required warnings from Annexes III to VI (applies to specific ingredients).

Warnings are written in the language required by the laws of the Member State where the product will be sold.

If impossible to include for practical reasons, warnings should be listed on outer packaging or an enclosed or attached leaflet, label, tape, tag or card.

05 Batch/Lot Number

Batch, Lot number, or any reference number that enables recognition of the production series is provided.

06 Country of Origin

The phrase “Made in …” is included. This applies to cosmetic products imported into the EU/UK or produced outside the EU/UK.

07 Ingredients List

Preceded by the word “Ingredients:”.

All ingredients listed using INCI nomenclature (verify the names using CoSing database).

The list follows the correct order based on the QQ file and includes all ingredients and allergens.

If impossible to include for practical reasons, the INCI list should be listed on outer packaging or an enclosed or attached leaflet, label, tape, tag or card.

08 Expiry Date

Expiry date is indicated for products with a durability of under 30 months.

Expiry date is marked with the “hourglass” symbol or the phrase “best used before the end of…”.

“best used before the end of…” is written in the language required by the laws of the Member State where the product will be sold.

Expiry date format: Month/Year (MMYY or MMYYYY) or Day/Month/Year (DDMMYYYY or DDMMYY).

Not mandatory for products with durability over 30 months.

Not mandatory for products from the "low-microbiological risk" group (check ISO 29621:2017-04 guidelines).

If durability requires special storage/usage conditions, this information is included.

09 Period After Opening (PAO)

PAO is indicated for products with durability over 30 months.

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11 The Open Book Symbol

The Open Book Symbol is included if any label information is provided on an enclosed or attached leaflet, label, tape, tag, or card.

From *Formula Design to Launch* **– Let's Create** *Your* **Next Cosmetic Product Together**

Whether you're working on a new beauty product, preparing to launch across the EU or UK markets, or seeking expert support in cosmetic chemistry - this is the right place to start!

from concept to formula & regulatory roadmap

We'll work side by side to design your cosmetic product from scratch - shaping your idea, creating a custom formula, and ensuring everything meets regulations for a stress-free EU/UK launch.

ASK FOR A CUSTOM QUOTE →

regulatory reviews

No matter if your cosmetic products are just entering the EU/UK market or are already available there, compliance checks are key points to keeping up with the latest restrictions & rules.

GET A TAILORED PROPOSAL →

resources

After leading regulatory reviews for more than 190 cosmetic products, I`ve seen what works and what doesn`t.

My guides are filled with practical tips to help you navigate EU/UK cosmetic regulations with ease.

DOWNLOAD A RESOURCE →

1:1 sessions

A dedicated 60-minute consultation focused on your cosmetic project.

We`ll discuss your vision, review important details, and shape a clear plan to bring your product to life.

BOOK A POWER SESSION WITH PAULA →

Drop a message with a snippet of what support you need, and I'll figure out the best way to help →

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Dr Paula Walencik - The Go-To Platform for Cosmetics Regulatory Affairs

Dr Paula Walencik

disclaimer

I created this free guide to help you design a label for your cosmetic product. It's meant to give you clarity and a solid starting point, but the truth is that even the most carefully crafted publication cannot replace a comprehensive and customized review done by a qualified Regulatory Affairs Specialist.

There are countless ingredients you can work with and so many different types of cosmetic products you can create, which is why regulatory reviews need to be made on a case-by-case basis.

The author is not responsible for any outcome that comes from the information provided here.

For specific regulatory advice and consultation tailored to your project, situation, and product, please reach out to a qualified professional.

Think of this guide as a helpful resource, and please remember that it should not be considered a substitute for professional guidance from a qualified Regulatory Affairs Specialist.

based on

Regulation (EC) No 1223/2009 Of The European Parliament And Of The Council of 30 November 2009 on cosmetic products

Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products (OJ L 46, 21.2.1976, p. 1)

Commission Directive 78/891/EEC of 28 September 1978 adapting to technical progress the Annexes to Council Directives 75/106/EEC and 76/211/EEC on pre-packaging (OJ L 311 , 04/11/1978, p. 21)

Directive 2007/45/EC of the European Parliament & of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC (OJ L 247, 21.9.2007, p.17)

EN ISO 29621:2010 Cosmetics – Microbiology – Guidelines for the risk assessment and identification of microbiologically low-risk product