

The background of the entire page is an underwater scene. It features a vibrant blue ocean with numerous small, orange and white fish swimming around. In the foreground, there are large, branching coral structures in shades of orange and pink. Bubbles of various sizes are rising from the bottom, creating a sense of movement. In the center, a white tube of cosmetic product is shown with its cap removed, and a white jar of cosmetic product is shown with its lid off, with a cloud of white powder or foam rising from it. The text is overlaid on a semi-transparent white rectangular box in the upper half of the image.

COSMETIC HANDBOOK

MICROPLASTICS

Enforcement of the EU regulation
in the cosmetic industry



COSMED

THE FRENCH COSMETICS ASSOCIATION FOR SMEs

1. General Information

Regulatory reference

Regulation (EU) No 2023/2055 of 25 September 2023, known as the “microplastics” regulation, amending Annex XVII (Restrictions) entry 78 of the REACH Regulation.

Regulatory objective

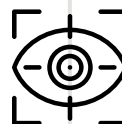
Regulation aims to reduce the intentional release of synthetic polymer microparticles (microplastics = SPM) into the environment.

To this end, **it prohibits the placing on the market of substances or mixtures (including cosmetics) containing more than 0.01% SPM by weight, subject to specific exemptions (derogations)**, with staggered application dates starting from 7 October 2027.

 Unintentional presence of SPM (manufacturing residues, cross-contamination, etc.) is not covered by this regulation.

Who is concerned?

- Suppliers of ingredients containing SPM
- Companies placing cosmetic products on the market
- Industrial users of SPM (e.g., manufacturing, packaging, storage)



2.Substances concerned

Firstly, it is important to determine whether the polymer meets the definition of SPM and is covered by this regulation. The definition and exclusion criteria must be taken into account.

No official list available

There is no official exhaustive list of polymers covered by the regulation. **Compliance is based solely on the analysis of the technical criteria defined by the regulation (composition, shape, size, solubility, biodegradability, etc.).** It is therefore up to each operator to characterise their substances on a case-by-case basis to determine whether they meet the definition of microplastics within the meaning of Regulation (EU) 2023/2055.

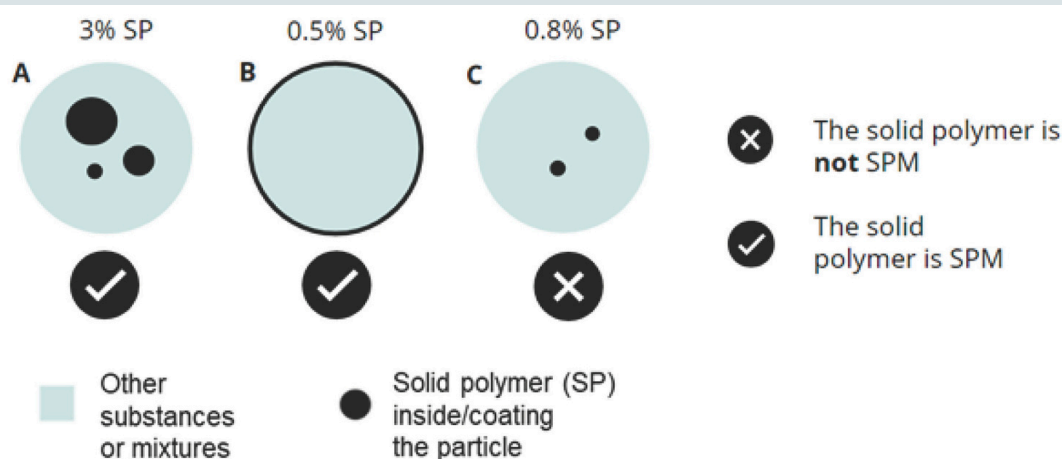
Which micro-particles?

This applies to synthetic (or natural but chemically modified) polymer microparticles that are intentionally added and simultaneously meet the following criteria:

- These are solid polymers:
 - either contained in particles and representing at least 1% by weight of those particles. (Figure A)

IF If several different microplastics are contained in the same particle, the sum of the concentrations of these different solid polymers is taken into account. If this sum reaches 1%, then the combination of these polymers constitutes an SPM.

- either build a continuous surface coating on particles (in this case, no concentration limit). (Figure B)
- **And** at least 1% by weight of these particles must meet at least one of the following size criteria:
 - all dimensions ≤ 5 mm,
 - or a length: ≤ 15 mm with a length/diameter ratio > 3 (fibrous particles).



Source: Norwegian Environment Agency. Modified by the European Commission.

Temporary lower limit

The regulation defines what constitutes an SPM, particularly in terms of particle size: the regulatory definition of synthetic polymer microparticles covers all particles smaller than 5 mm.

However, in practice, it is currently very difficult to reliably measure very small particles, particularly those smaller than 0.1 μm .

For this reason, the regulation provides for a temporary "technical" size limit to facilitate enforcement of the regulation pending advances in measurement tools, namely:

- $\geq 0.1 \mu\text{m}$ for "classic" particles (spherical or regular in shape)
- $\geq 0.3 \mu\text{m}$ for fibres (elongated shapes)

Below these sizes, the absence of detection does not mean that there are no microplastics, but rather that they cannot yet be reliably quantified with current tools.

If the presence of particles smaller than these thresholds can be proven, the restriction applies as long as they meet the criteria of the definition.

Key point: The thresholds of 0.1 μm (particles) and 0.3 μm (fibres) serve as a practical minimum reference pending the development of more advanced methods.

Exclusions

All polymers are not automatically considered as SPM within the meaning of the regulation "microplastics" regulation. Certain types of polymers are excluded, provided they meet one of the following criteria:

NATURAL POLYMERS NOT CHEMICALLY MODIFIED

Article 3.40 of the REACH regulation + clarification provided in the ECHA guidance

BIODEGRADABLES POLYMERS

CARBON-FREE POLYMERS

eg. siloxanes, minerals, etc

WATER SOLUBLES POLYMERS

More than 2 g/L
(cf. annex 16)



The mere mention of "biodegradable" on a technical data sheet is not sufficient.

The assessment of biodegradability must be carried out under rigorous conditions (choice of medium, duration, inoculum, test material, etc.) and performed in an accredited laboratory. The recognized testing methods that can be used to demonstrate biodegradability are described in Annex 15 of the regulation.



If you believe that an ingredient is excluded, have this hypothesis validated by an analytical expert.



3. Understanding the marketing derogations applicable to our sector

If your polymer is in line with the definition of a microplastic and constitutes more than 0.01% of your product, **the second step** is to determine whether you qualify for an exemption.

If so, you can continue to use your polymer, but you will then be subject to a reporting requirement, and potentially a labeling requirement for the raw material or finished product.

Criterion 4a: placed on the market for use at industrial sites

An exemption is provided for substances containing **SPM** when they are used **exclusively in an industrial environment, i.e. in controlled processes or on industrial sites, such as in the manufacture of cosmetic products.**



Any use outside of a genuine Industrial site, including artisanal production, is considered professional use and is not eligible for this exemption.



1

Provide clear information

The supplier of the SPM must indicate whether it contains SPM or constitutes an SPM, as well as providing information on the identity and quantity of the polymers. The supplier must also provide information on the conditions relating to its storage, use and disposal (IFUD – Instruction for Use and Disposal). This information may appear on the safety data sheet (SDS), the product packaging or the package leaflet, or it may be printed directly on the product label. The labelling must also state: *“The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.”*

2

Reporting annually to ECHA on the manufacture and/or use of substances containing SPM (or substances that are SPM themselves)

This obligation applies to two categories of actors.

- The supplier of the substance;
- The user of the substance at an industrial site (e.g. a manufacturer).

Each must make an annual declaration including: their use of the substance; the applicable derogation; a description of the use; the function(s) of the polymers; the site(s) concerned; generic information on the identity of the SPM; an estimate of emissions.

Criterion 5b: Loss of microplastic appearance during use

This exemption applies when SPM permanently lose their physical characteristics, such as shape, rigidity and solid structure, during their intended end use. They do not undergo encapsulation or simple trapping; instead, they undergo an irreversible transformation during application.

Conditions on eligibility:

The SPM is present in the initial product, but it changes form irreversibly during use to the extent that it can no longer be considered a microplastic once applied.



The transformation must be immediate and permanent, with no possibility of returning to the initial state: it must not be partial or temporary.

Examples:

- Hairspray: the polymer is an SPM in the aerosol but forms a flexible, continuous, non-particulate film on the hair after application.
- Nail varnish: the SPM in the liquid formula transform into a rigid, continuous layer after drying

1

Mandatory "IFUD" labelling on the finished product

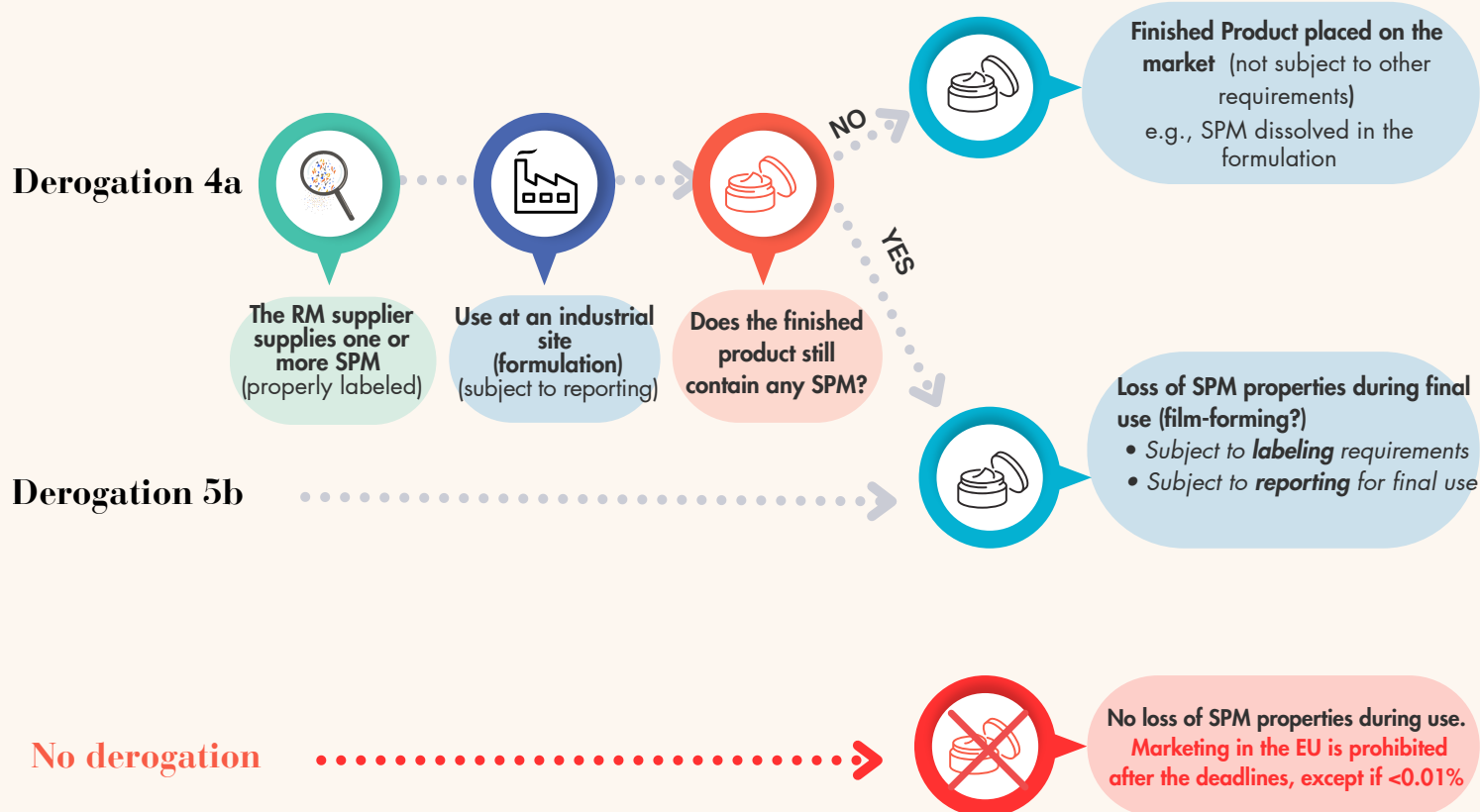
To prevent any release of SPM into the environment, the product must include instructions for use and end-of-life management (IFUD).

2

Annual reporting to ECHA

The marketer must make the following declarations annually: The use of the product, the applicable derogation, a description of the use, the function(s) of the polymers, the site(s) concerned, generic information on the identity of the SPM, an estimate of emissions.

Illustration of derogations



Cases involving multiple derogations:

Case 1: Several derogations apply to an SPM, with several actors in the value chain involved.

> Each actor must comply with their specific obligations, depending on their role and the derogations concerned.

Case 2: The same actor is affected by several derogations applicable to an SPM.

> This actor must ensure compliance with all the requirements associated with each applicable derogations.

4. Implementation schedule

 **Single date for placing on the market and making available**

LABELLING OF FINISHED PRODUCTS covered by derogation 5B.

They must bear either the words "*do not rinse before disposal*" or the pictogram, , unless there is no risk of release (i.e. if they are in a sealed package).

OCT. 17
2025

MANDATORY LABELLING of RM for industrial use (criterion 4a), including the statement: "The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council" Information on use, disposal, quantity and description of the microplastics present must also be provided.

 Non-compliant products/RMs must be removed from store shelves.

2027

REPORTING OBLIGATION applies before 31 May each year.

- For raw material **manufacturers** covered by Exemption 4a
- For **users** at industrial sites (criterion 4a exemption).
- For FP **marketers**, only if the microplastic is exempted by criterion 5b.

Note: this obligation will apply from 2026 to users of microplastics in granular form (e.g. blown packaging).

OCT. 17
2027

BAN on microplastics in **rinse-off** products with a maximum content of 0.01%.

OCT. 17
2029

BAN on microplastics in **leave-on products** (excluding makeup, lip, and nail products) (maximum content 0.01%).

OCT. 17
2031

Makeup, lip and nail products containing microplastics at a concentration of more than 0.01% must bear the statement "*This product contains microplastics*".

OCT. 17
2035

BAN on microplastics in makeup, lip, and nail products (maximum content 0.01%).

Note that plastic microbeads and loose glitter have been banned since 17 October 2023.

5. Summary of labelling requirements and implementation schedule

Type of products	Required information	Display terms	Regulatory deadline
Industrial-use RM (Derogation 4a)	"The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council" Additional information on: usage and disposal instructions, quantities, and a description of the microplastics present.	To be determined according to the nature of the product (technical data sheet, safety data sheet, packaging, label, leaflet, or other written medium intended for the industrial user)	From 17 October 2025
Finished products under Derogation 5b	For use and disposal Instructions (IFUD) Example: <i>"Do not rinse before disposal"</i>, symbol proposed by Cosmetics Europe  Note: The IFUD applies to all types of packaging. Only sealed packs are exempt from the IFUD labeling requirement, provided that the risk of microplastic release into the environment is nonexistent under normal conditions of use.	- On the packaging or in the leaflet, close to the end-of-life instructions (e.g., best before date, PAO) - Format: clear, legible, indelible text or pictogram - To be translated into the official languages of the country of sale - May be supplemented by a digital support (QR code, website, app)	From 17 October 2025 For both placing on the market and making available Single date!
Lip, nail, and makeup products containing SPM (not exempted)	<i>"This product contains microplastic"</i>	- On the packaging or in the leaflet, close to the end-of-life instructions (e.g., best before date, PAO) - Format: clear, legible, and indelible text - To be translated into the official languages of the country of sale - May be complemented by a digital support (QR code, website, app)	From 17 October 2031 For both placing on the market and making available Single date!

6. Good compliance practices

Assessment

- Conduct a systematic assessment of the polymers used and the raw materials portfolio to identify those that contain SPM.
- Assess formulations against applicable exclusion or derogation criteria.
- Regularly monitor the guidelines published by the European Commission.

Collaboration

- Establish close dialogue between RM suppliers and formulators.
- Strengthen cross-functional collaboration between the regulatory, supply chain and R&D departments.

Action

- Update Safety Data Sheet (SDS) and packaging by incorporating the required information (e.g. IFUD).
- Understand how to fulfil reporting obligations and prepare for them.
- Update subcontracting agreements to clarify the roles and responsibilities of each stakeholder in managing the assessment and implementation of the “microplastics” regulation.
- Manage reformulations.

ANTICIPATE

**how long it will take
to complete all
assessments**

INCORPORATE

**the implementation
deadlines set out in
the regulation**

7. Frequently asked questions

What does reporting involve?

It is a declaration that must be submitted to ECHA in order to provide the authorities with certain information on the use of, and placing on the market of, microplastics that have been intentionally added to products. This system enables the authorities to monitor the use of microplastics more effectively, assess environmental risks, and verify compliance with applicable restrictions. Reporting must be done annually via the IUCLID platform.

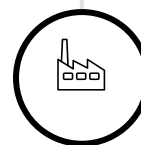
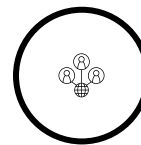
Which industrial uses are covered by derogation 4a?

Use is defined in point 24 of Article 3 of the REACH Regulation as *“any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation”*.

All of these actions are therefore subject to reporting requirements if materials within the scope of the regulation are involved.

Please note that if a bulk cosmetic product contains SPM, the packaging stage at an industrial site is in scope.

In the case of transport between two industrial sites, emissions must be reported by the party responsible for the goods at the time they occur.



Is there a quantity threshold below which reporting is not required?

No, any use that is subject to the reporting obligation must be declared, regardless of the quantity involved.

How should a relevant IFUD be chosen?

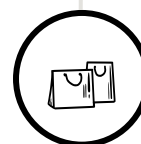
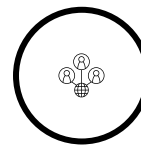
The regulation does not specify the wording of instructions for use and disposal (IFUD). You can use the Cosmetics Europe recommendation "Do not rinse before disposal" (or a pictogram) as it is or adapted for your product. The IFUD is considered appropriate for preventing SPM release when using the product. Only the competent authorities can assess compliance.

Does the Regulation apply to unintentionally present microplastics?

No, only those that are intentionally added and/or used are covered by Regulation (EU) No 2023/2055.

I am a distributor. Do I have a reporting obligation?

No, reporting obligations only apply to manufacturers of raw material, finished product manufacturers, and responsible person. Retailers are not subject to this obligation.





8. Useful links

- [COMMISSION REGULATION \(EU\) 2023/2055 of 25 September 2023 amending Annex XVII to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) as regards synthetic polymer microparticles](#)
- [European Commission explanatory Guide: Implementation of the Microplastics Regulation](#)
- [ECHA – Regulatory Support](#)
- [National REACH Regulatory Assistance Service](#)

For subscribers to the Cosmed regulatory monitoring service:

- [EU - REACH Regulation on synthetic polymer microparticles \(microplastics\)](#)
- [EU – REACH / ECHA – Practical guide on reporting under Regulation \(EU\) No. 2023/2055 on synthetic microplastics](#)

COSMED Regulatory

cosmetic, chemical and
environmental regulations
of the sector



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