



Annel

MICROPLASTICS

UK & EU

REQUIREMENTS

09/2023

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EU & UK

Key terms

Plastic - synthetic and water-insoluble polymers, easy to modulate, extrude or physically manipulate. Plastic is a commonly used material to form and maintain various forms and shapes. The biggest concern about plastic is its non-biodegradable character and inability to biodegrade.

Plastic materials may break down into smaller fragments, called microplastic.

Microplastic - any kind of tiny, solid, and water-insoluble plastic material, usually in the form of a **particle or fibre**. The precise upper size limit is still under evaluation. Commonly considered size is equal or below a 5 mm diameter in any dimension.

Microplastics can be produced intentionally or come from the degradation of bigger materials. The “**primary microplastic**” defines the former case, while “**secondary microplastic**” refers to products of polymer degradation.

The problem of microplastic pollution is increasing and involves different environmental compartments, mainly water (including also the drinking water sources).

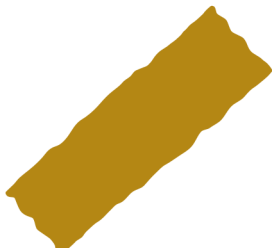
Microbeads - any intentionally developed and water-insoluble plastic particles with 5 mm or less in size. Microbeads are used in the production of rinse-off personal care products to deliver effective exfoliating properties.

Synthetic polymers vs. natural polymers

Synthetic polymers (i.e. man-made polymers) are intentionally developed and synthesised using a variety of polymerisation reactions. Solid and water-insoluble synthetic polymers are used as plastic material. The most common examples are polyethylene, polystyrene, polypropylene, Teflon etc.

Natural polymers are macromolecules developed in nature by biosystems. Natural polymers are usually isolated from bacteria, fungi or plants and less frequently from animal sources. Examples of natural polymers are DNA, cellulose, silk, hyaluronic acid, keratin, collagen and many other proteins and polysaccharides.

Natural polymers decompose yielding ingredients such as amino acids or glucose, crucial for the homeostasis of living organisms. These products indicate high biocompatibility towards all living organisms and environments.



Microplastic - accumulation, pollution and risk

- each year around **42 000 tonnes of microplastics** are released into the environment after the use of products containing them;
- each year around **176 000 tonnes of microplastics** are unintentionally released into the European surface waters - sources of drinking water;
- each year **145 000 tonnes of microplastics** are used in the EU/EEA countries.

European Commission Statement and Decision by the EU Members States

Currently (August 2023), there is no European law that covers the problem of microplastic pollution. Also, there are no restrictions for the industry to reduce the production and release of microplastics to biosystems.



June 2020 - ECHA's Committee for Risk Assessment (RAC) adopted its opinion with a recommendation to ban the use of microplastics

August 30, 2022 - European Commission presented an official proposal to amend the REACH Regulation regarding the production and release of microplastics

April 26, 2023 - REACH Committee voted in favour of the Commission's proposal

Before the restriction will be adopted, it needs to be scrutinised by the European Parliament and the Council.

Key elements of the proposed regulation*

**Annex XV dossier proposing restrictions on intentionally added microplastics - draft proposal by ECHA*

The regulation defines microplastics as any solid, water-insoluble polymer in the form of microparticles or microfibers.

Microplastics can be used as a substance on their own or in the mixture in a concentration $\geq 0,01\%$ by weight

The goal is to progressively eliminate microplastics from everyday products like cosmetics, fragrances and home cleaners.

The initiative involves:

- develop labelling, standardisation, certification and regulatory measures on unintentional release of microplastics;
- increase the monitoring and capture of microplastics at all relevant stages of products' lifecycle;
- further develop and harmonise methods for measuring unintentionally released microplastics.



Implementation deadlines and transitional periods

4 years - rinse-off cosmetic products;

5 years - detergents;

6 years - encapsulated fragrances;

12 years - leave-on makeup products, such as lipsticks and nail polish**



**** 12 years is the total transitional period but 8 years after publication of the restriction the claim: “this product contains microplastic”** will be mandatory for those leave-on makeup products and nail polish that still contain microplastics

Criteria for microplastic according to the ECHA proposal

- **Polymers** - either on their own or in coatings - at least 1% of the particles meet the microplastic definition

Non-microplastic particles can become microplastics if they have a coating, of any thickness, which meets the microplastic definition

- **Specific size** - dimensions of particles are equal or less than 5mm; no lower size limit, however lower limit of 100nm is included if quantification is scientifically impossible
- **Contain carbon atoms**
- **Solid - solubility criteria** - polymers that have a solubility lower than 2 g/L; solubility test need to be performed by GLP laboratory; permitted procedure are OECD Guideline 120 and OECD Guideline 105; test material has the same physical characteristics as the polymer in product; **if using a blend of polymers, both the individual polymer and the blend need to be tested;**
- **Synthetic**
- **Non-biodegradable**



Microplastic is a material that meets all of the above criteria.

INCI is not defining microplastics.

The same INCI name could be a film-former, a solid, a wax, or substance dissolved in different formulations

Derogations from the criteria

Banned products -ifthe products release microplastics into the environment;

Not banned products* -ifthe microplastics lose their characteristics before the product enters the environment

*However - instructions for use, labelling and reporting requirements in place to ensure microplastics are not released into the environment; the instructions can be added as text or pictograms; yearly reporting to ECHA about such products will be also mandatory

Obligations for manufacturers and suppliers of ingredients meeting the microplastic criteria

Yearly reporting to ECHA will be mandatory (onlyfirst actor in the supply chain should report to ECHA)



Every report must include

- description of the uses of microplasticsfor the previous year;
- generic information about the identityof the polymers (however authorities may request more precise information)
- an estimate quantity of each microplastic type released to the environment the previous year;

Case Study 1

Manufacturer purchases a raw material from Supplier. This raw material meets the criteria of microplastic.

Manufacturer uses this raw material for formulation and as formulated the raw material is no longer solid.

Conclusion The final product of the manufacturer does not contain microplastic (a solid particle) thus it is out of the scope of the restriction. However, microplastic material was used at the industrial site, hence manufacturer has reporting obligations about this material to ECHA.

The raw material provided by Supplier meets the criteria of microplastic and it is within the scope of the restriction and reporting obligations.

Case Study 2

Cosmetic product contains polymer X

Polymer X is a microplastic according to the definition in the restriction

Polymer X forms a film, which loses its microplastics characteristics at point of use

Conclusion

The final cosmetic product is a subject to derogation 5b because the microplastic loses its characteristics at point of use

The are reporting and labeling obligations fr this product.

If such a product is manufactured outside the EU and imported by a brand owner (EU RP):

- there are NO reporting to ECGA and NO obligations at the factory site;
- NO instructions for use and disposal are required;
- technical information to help downstream user meet their legal obligations e.g. polymer identity and concentration in the product;

Statement and Decision by the EU Members States

Several countries **have already enacted or proposed national bans on intentional uses of microplastics in consumer products** . The bans concern mainly the use of **microbeads in rinsed-off cosmetics**, in which the microplastics are applied as abrasive and polishing agents.



2014 - A ban on the import, manufacturing and sale of cosmetic products containing microbeads has come into force in **the Netherlands**



1 January 2018 - A ban on the import, manufacturing and sale of rinse-off products containing microbeads has come into force in **France**



1 January 2019 - A ban on the import, manufacturing and sale of rinse-off products containing microbeads has come into force in **Sweden**



1 January 2020 - A ban on the import, manufacturing and sale of rinse-off products and detergents containing microbeads has come into force in **Italy**



20 February 2020 - A ban on the import, manufacturing and sale of rinse-off products containing microbeads has come into force in **Ireland**



Statement and Decision in the UK

The EU draft microplastics restriction will only be applicable in the EU and Northern Ireland. Great Britain has a separate chemical framework, UK REACH, under which the UK agency (the Health and Safety Executive – HSE) will carry out an evidence project to understand which regulatory measures are more suited for microplastics placed or used on the GB market. Therefore, this restriction will not automatically be implemented in GB.



9 January 2018 - A ban on the import, manufacturing and sale of rinse-off products containing microbeads has come into force in the UK

Doubts and most frequently asked questions

About criteria whether a polymer is a microplastic exclusive

The polymer will be classified as a microplastic and will be in the scope of the restriction, if it meets all the following criteria: polymer, either on its own or forming a coating, of a specific size, containing carbon atoms, solid, synthetic, non-biodegradable.

If one of these criteria is not fulfilled, the polymer is out of scope.

About cosmetic ingredients and how they are impacted by the microplastics restriction

There is no list of ingredients within the scope of the EU REACH microplastics restriction.

The restriction is based on the physical and structural features of substances, rather than their chemical or INCI names.

About the biodegradability test and its duration

The Appendix to the Annex of the draft microplastics restriction provides the list and details of biodegradability test methods, which include the length criteria for the test.

About raw material and how to determine whether it should be considered microplastic

The biodegradation testing (Appendix to the restriction Annex) is required to prove that a raw material is biodegradable, and therefore out of scope of the restriction.

The test material shall be comparable in terms of composition, form, size and surface area to the polymer particles present in the product or, if not technically feasible, to the particles that are disposed or released to the environment.

About reporting to ECHA - estimated release of microplastic or amount used for manufacturing?

Companies shall report to ECHA the estimated amount of microplastics released into the environment, not the estimated amount of microplastics used.

Who is responsible for reporting to ECHA brand owner or the RP with outsourced obligations and third-party consultancy company?

This will be a decision between the two parties. First of all, it is important to check that no other actors further up in the supply chain are already reporting the same information to ECHA.

If the reporting obligations fall to the RP, then the brand owner and the third-party consultancy acting as the RP shall agree between themselves who shall carry out the reporting to ECHA.

“Microplastics free” claims - UK and EU

“Microplastics free” claims for cosmetic products must follow the same requirements as all other cosmetic claims, including Article 20 of both the UK and EU Cosmetic Products Regulation, the Common Criteria for Cosmetic Claims Regulation (which is still applicable in the UK) and the EU Unfair Commercial Practices Directive as implemented in the UK with the Consumer Protection from Unfair Trading Regulations 2008.

The 6 Common Criteria for Cosmetic Claims Regulation:

- 1 **Legal Compliance;**
 - . **Truthfulness;**
- 2 **Evidential Support;**
 - . **Honesty;**
- 3 **Fairness;**
 - . **Informed Decision-making.**

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Considering the ban on microbeads in rinse-off products implemented in the Netherlands, France, Sweden, Italy, UK and Ireland, products placed on the markets of these countries with the “Microplastics free” claims would be in breach of the Legal Compliance common criterion.

References:

https://environment.ec.europa.eu/topics/plastics/microplastics_en

<https://echa.europa.eu/en/hot-topics/microplastics>

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC