IPEC FEDERATION

The International Pharmaceutical Excipients Council

Best Practices for European REACH Restriction on Synthetic Polymer Microparticles

for Pharmaceutical Excipients

Version 1
2025

This document represents voluntary guidance for the excipient industry and the contents should not be interpreted as regulatory requirements. Alternatives to the approaches in this guide may be used to achieve an equivalent level of assurance for excipient quality.

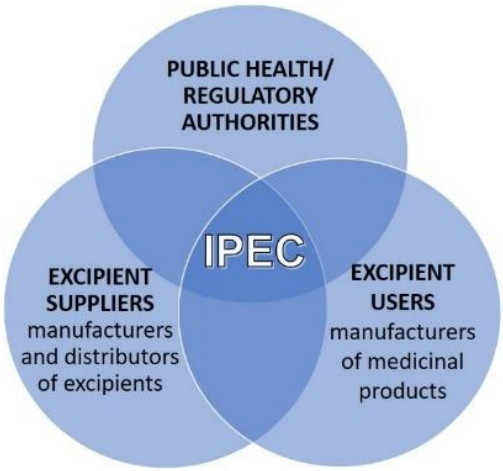
This guide was created to help companies understand current expectations on this topic and is not intended for use by third party certification bodies to conduct audits or to certify compliance with the guide.

FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient **manufacturer**s, **distributor**s, and end-users. At the current writing there are regional pharmaceutical excipient industry associations located in the Americas, Europe, Japan, China, and India. IPEC's objective is to contribute to the international excipient standards development and harmonization, provide information useful for new excipient development and introduction, and offer best practice and guidance concerning excipient development.

IPEC has three major **stakeholder** groups:

1. Excipient manufacturers and distributors, defined as **supplier**s in this document,
2. Medicinal (drug) product manufacturers, defined as *excipient users* in this document, and
3. Public health and regulatory authorities.



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This guide is intended to be voluntary, to indicate best practice, and to be globally applicable. However, it should be recognized that the laws and regulations applying to excipients will vary from region to region and country. In addition, the rules and regulations are continually evolving. It is the responsibility of the reader to review the most current version of any applicable regulatory requirement. Versions referenced in the guide were based on versions available at the time the guide was published.

In this guide, pharmaceutical excipient(s) will be referred as excipient(s). This guide may be applied to veterinary medicines, as appropriate and include reference to specific veterinary guidance and regulations.

Throughout the guide, **justification** implies that a decision is made based on scientific, quality and/or regulatory considerations.

This guide offers best practice and guidance for preparing and sharing microparticle data needed to justify certain excipient derogations that could apply to **REACH** restriction of **synthetic** polymer microparticles [1] and offers a streamlined process for ensuring compliance with regulatory requirements for both polymer manufacturers, suppliers and downstream industrial users who are typically drug product manufacturers.

This document should be read in conjunction with:

- The Regulation - Annex XVII of EC 1907/2006 Entry 78 (EU 2023/2055)
- The Guidance - REACH restriction of synthetic polymer microparticles (Entry 78 of Annex XVII REACH, as introduced by Commission Regulation (EU) 2023/2055) –
    - Explanatory Guide Part I - Narrative
    - Explanatory Guide Part II – Q&A
    - Explanatory Guide Part III – Annexes
- The Reporting Requirements - Implementation of the reporting requirements of the REACH restriction on microplastics. Reporting Requirements Final ECHA Apr 2025 v1.1

NOTE: Refer to the "International Pharmaceutical Excipients Council Glossary: General Glossary of Terms and Acronyms" for definitions [2].

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Table of Contents (TOC)

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
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Table of Tables

Table of Figures

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
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This guide was developed by representatives of the associations which constitute the IPEC Federation (IPEC). The IPEC Federation greatly appreciates the many hours devoted by the core team of individuals and other contributors listed below, to make this guide available to IPEC members and the broader excipient community. Equally, IPEC extends its thanks to the employers of those same contributors who provided the necessary time and resources, without which, this guide would not be possible.

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1 INTRODUCTION

In 2023 the European Commission (EC) published Commission Regulation (EU) 2023/2055, amending Annex XVII to Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No. 1907/2006. The update included a new restriction in Entry 78, which concerned synthetic polymer microparticles (SPMs). The entry stated that SPMs cannot be used when "they are present to confer a sought-after characteristic in **mixtures** in a concentration **equal to or greater than 0.01% by weight** of the mixture.

Medicinal products for human and veterinary use are **exempt from the prohibition** of placing synthetic polymer microparticles (SPM) on the market under Paragraph 1, as per **Paragraph 4(b)** of Entry 78. Pharmaceutical ingredients (i.e. excipients and **API**s) that are not yet included in the medicinal product cannot benefit from derogation 4(b), but if they are used at an "industrial **site**" (e.g. in the formulation of a medicinal product) they benefit from derogation under 4(a) [3, 4].

A high-level summary of regulatory requirements for medicinal products is summarized in table below:

Table 1: Regulatory Requirements for Medicinal Products

Product Type	Market Ban	Use/Disposal Information Required?	Reporting Required
Finished Medicinal Products	Exempt (paragraph 4(b))	No	Yes (paragraph 12)
Pharmaceutical Ingredients (not yet in finished products**)**	Yes, unless used at Industrial sites	Yes (If under paragraph 4(a)	Yes (Paragraph 11)

1.1 Purpose

The intent of this guide is to highlight areas where data may be needed to justify certain derogations that could apply to excipients and a streamlined process for ensuring compliance with regulatory requirements for both polymer manufacturers, suppliers and downstream industrial users who are typically drug product manufacturers. Polymers are generally complex macromolecules and there is an enormous diversity in their chemistry and properties. The data on polymeric excipients may not always be available and there are significant technical challenges such as manufacturing methods, physical chemical properties and other factors may result in differences between suppliers, and **grade**s within a polymer family. An effort has been made to present a methodical approach and interpretation of specific clauses which should be helpful to the medicinal products segment in assessing elements important for compliance with regulations.

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1.2 Scope

This guide is applicable to excipients used in the manufacture of human and veterinary medicinal products as related to 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.

1.3 Principles Adopted

This is an international guide and focuses on the European microparticles restriction which applies to excipients and medicinal products manufactured in and/or imported into Europe with enforcement being conducted at member State level. As such it cannot anticipate all national enforcement interpretations nor cover in detail the characteristics of every excipient.

When considering the use of this guide, manufacturers and distributors should consider how it may apply to that specific organization's product. The diversity of excipients means that some principles of the guide may not be applicable to certain products and processes. The term "should" indicate recommendations that are expected to apply unless shown to be inapplicable or replaced by an alternative that provides at least an equivalent level of quality assurance. Note that "should" does not mean "must" or "shall".

This guide includes notes that offer common examples for interpretation and implementation without adding further requirements. Notes are not intended to contain an exhaustive list. They are presented as indented, *italicized* blue text.

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2 DEFINITION OF SYNTHETIC POLYMER MICROPARTICLES

Synthetic polymer microparticles (SPMs) are defined as polymers that are solid and which either are contained in particles and constitute at least 1% by weight of those particles, or build a continuous surface coating on particles, where at least 1% by weight of those particles fulfil either of the following conditions:

- All dimensions of the particles are equal to or less than 5 mm;
- The length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3.

2.1 Key points

There are 3 fundamental requirements that need to be assessed for SPM Classification:

1. **Polymer Characteristics**: Must be carbon based solid, synthetic non-degradable, and insoluble.
2. **Physical Form**: Must be either:
    - Contained in particles (≥1% w/w of the particle), or
    - Form a continuous surface coating on particles.
3. **Size Threshold**: At least 1% by weight of the particles must be ≤5 mm in all dimensions (or ≤15 mm in length for fiber-like particles with a length-to-diameter ratio >3). Generally, fiber particles are not common in pharmaceutical applications. An example would be ethyl cellulose which is fibrous in nature.

The restriction applies to SPM that are **intentionally present in mixtures** to confer a **sought-after characteristic**. This means SPM are added on purpose to provide a specific property or function to the product (e.g., color, texture, water absorption, abrasiveness, etc.). SPM that are present in a mixture **unintentionally** (e.g., as impurities from breakdown of packaging or larger objects, byproducts etc.) are **not** within the scope of the restriction. Only SPM added for a functional reason are regulated. For example,

- SPM providing a certain consistency, texture, fragrance or colour to a cream, a detergent or any other product; or
- SPM used as binder, filler, diluent, lubricant, disintegrant, coating, etc. in solid oral forms of medicinal products (e.g. tablets).

Note that both excipients that are solid polymers and finished oral **dosage form**s may meet the requirements of SPM. The responsibility for the provision of information that supports and/or excludes classification as SPM in order to make compliance decisions is summarized in the table below:

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Table 2: Provision of information that supports and/or excludes classification as SPM

	Data Elements	Excipient Manufacturer/ Supplier	Drug Product Manufacturer
a	Excipient meets definition of a microparticle	X	
b	Excipient is liquid/does not meet definition	X	
c	Particle dimensions do not meet definition	X	
d	Particles do not constitute 1% by wt./continuous coating	X	
e	Tablet/Capsule meets/does not meet definition of SPM	X (for capsules)	X

2.1.1 Excipients

Excipients meeting the 3 conditions of the SPM definition will be considered synthetic polymer microparticles and **excipient supplier**s will need to communicate this to downstream industrial users. Information may be provided in SDS, COA, or other appropriate documentation.

If an excipient does not meet all 3 conditions above and is therefore not a microparticle, information supporting that determination should be communicated to the downstream industrial user by the supplier on request to support their assessment of the finished drug product.

2.1.1.1 **Application of SPM Criteria to Dosage Form**

Tablets, pills, and granules are considered particles under the restriction. Specifically, a tablet is regarded as a particle if it meets the particle definition, "*minute piece of matter, other than single molecules, with defined physical boundaries*" under Paragraph 2(a) of the regulation. It does not matter whether the tablet, pill or granule is a solid mixture; solid mixtures can be particles and the two terms are not mutually exclusive. Any synthetic solid polymers in or on these dosage forms are classified as SPM if certain conditions are met.

- Are synthetic or chemically modified natural polymers
- Are solid, non-degradable, and insoluble
- Are present in or coat particles (e.g., granules within the tablet and/or capsule)
- Meet the size and concentration thresholds (≥1% w/w in particles, and ≥1% of particles ≤5 mm or ≤15 mm for fibers)

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This interpretation aligns with the illustrative examples in Part I, Section 2 of the EC guide [5], where tablets and/or capsules with internal granules or coatings are used to demonstrate how SPM criteria apply.

The EC guidance provides details concerning solid polymers in the tablet core, such as granules, powder, crystals or flakes, or other solid particles. If the tablet core (or, more generally, the mixture) does not contain particles, then the polymers in the core are not SPM. When assessing compliance with the third condition (particle size), it should be kept in mind that, in a **batch** of particles containing or coated by solid polymers, **it is sufficient that at least 1% of the particles fulfils the size requirements for all particles to be considered as fulfilling that criterion**. What this means in practice is that if only 1% by weight of the particles under consideration (i.e. containing at least 1% by weight of solid polymers or coated by them) are smaller than 5 mm in all dimensions - or are shorter than 15 mm, if they have a length-to-diameter ratio > 3, and the remaining 99% by weight are bigger than 5 mm - or longer than 15 mm, if they have a length-to-diameter ratio > 3, then the solid polymers in the totality of those particles would be considered SPM and fall in the scope of the restriction (including the polymers in the 99% of particles that are bigger than 5 mm, or longer than 15 mm if they have a length-to-diameter ratio > 3).

Generally, pharmaceutical excipients will be less than 5 mm in diameter including fibers that will meet the size requirements. This may be more relevant to mini tablets or coated minitablets < 5mm that may be considered a SPM. Examples of tablets/capsules discussed below illustrate that it is important for the drug product manufacturer to understand the excipient properties in both the tablet core and coating (for coated applications). An SPM may be contained within the granules that have been manufactured containing other constituent excipients before being bound within the tablet. The internal granules may not necessarily be 100% solid polymer *per se*, but if the granules are under 5 mm and contain an SPM, then they are considered a reportable SPM. These examples emphasize that even if the tablet itself is large, internal **component**s or coatings may still qualify as SPM depending on their size and composition [6].

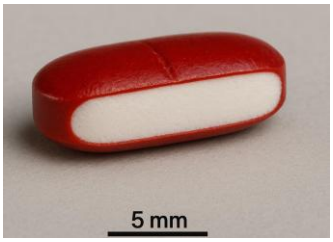

Figure 1: A tablet >5 mm with a continuous solid polymer coating → Not SPM, because the coated particle (tablet) exceeds the size threshold

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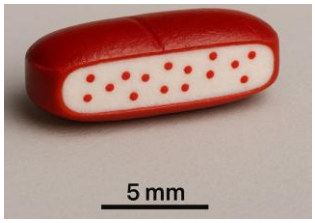

Figure 2: A tablet >5 mm with a coating and internal granules <5 mm made of 100% solid polymer → The coating is not SPM, but the internal granules are SPM

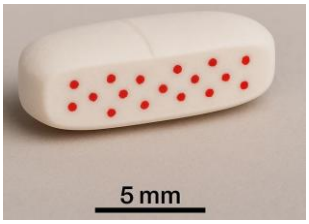

Figure 3: A tablet >5 mm with internal granules <5 mm and 100% solid polymer → The internal granules are SPM

Figure 4: A tablet <5 mm with a continuous solid polymer coating → The coating is SPM, regardless of concentration

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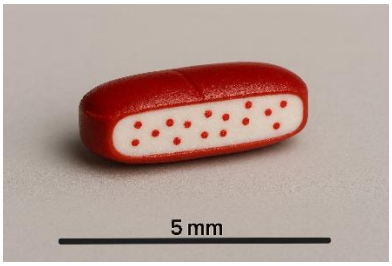

Figure 5: A tablet <5 mm with a coating and core containing 10% solid polymer → Both the coating and the internal polymer are SPM

2.2 Data Requirements

The SPM regulation contains references and appropriate information for collecting data to ascertain if an ingredient meets the definition of a solid, liquid or gas; particle size (out of microparticle defined range) and/or wt.% of SPM.

2.2.1 Data for Excipients:

Generally, it may be presumed that a solid polymer qualifies as a SPM unless the supplier provides evidence to the contrary. The excipient manufacturer should possess supporting documentation regarding the technology platform and/or excipient grade to determine whether the polymer is excluded from the microparticle definition based on criteria outlined in the above table. The Regulation outlines recommended methods; however, suppliers may employ other scientifically valid and justifiable approaches, provided these are acceptable under the REACH regulatory framework. Key references and applicable methods are provided in the sections below and should not be construed as an exhaustive list.

Particle size

For a particle to be in scope of the Restriction, all dimensions must be equal to or less than 5mm. This means:

- A particle with at least one dimension >5mm is not a SPM
- If **material** is a solid, block it does not meet the size criteria required to define the substance or mixture as SPM and therefore is out of scope of the Restriction

The EC guidance [1] provides references to ISO standards e.g. ISO 14644-1:2015 and ISO 21501-4:2018. It is also mentioned that techniques used for the characterization of nanomaterials could be useful for very small particles, e.g. dynamic light scattering (DLS) or

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field flow fractionation (FFF). The Restriction does not specify test methods to use for particle size determination.

References to USP/Ph. Eur. related to particles size are provided here. However, this is not an exhaustive list and the SPM supplier may use other valid sources and/or methods as deemed appropriate.

European Pharmacopoeia References:

- Ph. Eur. 2.9.38: Particle Size **Distribution** Estimation by Analytical Sieving
- Ph. Eur. 2.9.31: Particle Size Analysis by Laser Light Diffraction
- Ph. Eur. 2.9.50: Particle size Analysis by Dynamic Light Scattering

United States Pharmacopoeia:

- USP GC <429> Light Diffraction Measurement of Particle Size
- USP GC <430> Particle Size Analysis by Dynamic Light Scattering
- USP GC <786> Particle Size Distribution Estimation be Analytical Sieving
- USP GC <811> Powder Fineness

It is at the discretion of industry to determine a scientifically credible methodology.

Particle size distribution

Tablet granules size is typically measured by sieving and an example case is discussed in this section as there are a range of mesh sizes and components. Granules passing through either a 16 or 20 mesh screen would result in granule sizes of less than 5 mm, with the maximum size determined by the screen used—1.19 mm for 16 mesh and 0.84 mm for 20 mesh. Typically, most granules would fall within scope unless composed solely of soluble components (for example gelatinized starch). For formulations containing both soluble and synthetic polymer components, if the polymer granule content exceeds 1%, it is considered in scope.

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3 EXCIPIENT SCOPE

The table below summarizes the information needed to ascertain if an excipient is out of scope of the microparticle regulation and who is responsible for making that decision. If a pharmaceutical ingredient is claimed to be degradable or soluble, manufacturers must have supporting data in line with Appendices 15 and 16 of the microparticles regulation [1].

This information must be made available to competent authorities upon request.

Table 3: Information to ascertain if an excipient is out of scope of the microparticle regulation and who is responsible for making the decision

Data Elements	Excipient Manufacturer	Excipient User
Excipient is out of scope		
Natural, not chemically modified	X	
Biodegradable per appendix 15	X	
Soluble	**X**	

3.1 Natural Polymers

Polymers that occur in nature, by default, are considered inherently (bio)degradable in the environment and do not contribute to the microplastic concern. Therefore, they are not considered microplastics. Natural polymers are defined as the result of a polymerisation process **that has taken place in nature**, independently of the process through which they have been extracted and **are not chemically modified.**

3.1.1 Key Points:

The excipient supplier is required to state whether an excipient qualifies as a natural polymer that has not undergone chemical modification. Supporting documentation may be provided to downstream industrial users upon request for compliance purposes.

- According to REACH definitions, substances which occur in nature refer to naturally occurring substances that are either unprocessed or processed solely by manual, mechanical, or gravitational means, by dissolution in water, flotation, extraction with water, steam distillation, or heating only to remove water, or substances extracted from air by any method.
- A not chemically modified substance is defined as a substance whose chemical structure remains unchanged, even if it has been subjected to a chemical process or treatment, or a physical mineralogical transformation, such as the removal of impurities.

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- Polymers obtained by fermentation (a biotechnology process) are not classified as natural polymers, as the polymerisation occurs in an industrial environment and therefore does not meet the definition of a "…polymerisation process that has taken place in nature…".
- Information is available in Entry 78 of Annex XVII of REACH [1]; ECHA guidance on monomers and polymers, Chapter 3.2.1.3 [7]

3.1.2 Examples

Illustrative examples relevant to medicinal products are provided below:

- Guar gum, starch, locust bean gum, alginic acid etc.

3.2 Water soluble polymers

According to the SPM regulation, polymers that have a solubility of greater than 2g/L are considered soluble in water.

3.2.1 Key Notes

- Tests must be performed by labs compliant with GLP, ISO 17025 or other international standards accepted by ECHA
- Currently GLP is not a requirement for physicochemical endpoints under EU REACH.
- Testing should be carried out on material comparable in terms of composition, form, size, and surface area to the polymer particle present in the product.
    - If it is not technically feasible to test the particle, a test can be performed on the polymer itself
- The SPM regulation [8] states that Member State competent authorities may request "information" proving that derogated polymers are degradable or soluble in accordance with Appendix 15 and 16 respectively. It is not clear what constitutes "information" but in the Q&A Part II Q13.11 it infers that a lab test report is more likely to contain the evidence necessary than an SDS, but it is the responsibility of the manufacturer, importer or industrial downstream user to ensure proof of degradability is sufficient. Q13.11 only addresses degradability but it is a good indicator as to the approach that is likely to be taken for proof of solubility as well.

3.2.2 Data Requirements:

Appendix 16 [9] of the restriction details specific test guidelines, test conditions and pass criteria that must be followed to prove solubility in water:

Table 4: Test guidelines, conditions and pass criteria to prove solubility in water

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Permitted test methods	Test conditions	Pass criteria
OECD 105 OECD 120	○ Temperature – 20°C ○ pH – 7 ○ Loading – 10g/1000ml ○ Test time – 24 hours	>2g/L

3.2.3 Examples:

- Certain cellulose ethers are derogated based on solubility and more information may be available from specific manufacturers.
- The user should rely on information from the supplier's assessment about solubility data meeting the required regulatory criteria.

Formulation

Immediate release - coated (excipients included would be soluble)

Immediate release – uncoated (polymer in the core – wet granulation type polymer)

Gastro resistant/colonic coated (pH dependent solubility)

3.3 Polymers without carbon atoms in their structure

3.3.1 Key Notes

- Polymers without carbon in their structure (neither in their backbone nor in their side chains), are not subject to the restriction, regardless of their physical form or use.

3.3.2 Examples

- Examples include bentonite, kaolin, talc, and other clay minerals, etc.

3.4 Biodegradable Polymers

Polymers that are biodegradable are not in scope of the Restriction. The exact methodologies, test conditions and pass criteria are detailed in Appendix 15 of the Restriction.

3.4.1 Key Notes

- Tests must be performed by labs compliant with GLP, ISO 17025 or other international standards accepted by ECHA
- Testing should be performed under conditions that are comparable in terms of:
    - Composition, form, size and surface area in the product or,
    - If not feasible, the polymer particles as disposed of / released to the environment

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- Polymers used in encapsulation may be tested in any of the following forms:
    - In the form placed on the market
    - In the form of isolated coating
    - In the form placed on the market where the organic core of the material is replaced by an inert material
- Where the polymer is part of a mixture:
    - The test material contains more than one polymer
        - The test material and each polymer requires its own test; or
        - The test material can be tested as a whole as long as it can be proven that each of the polymers passes the criteria of the test carried out
    - The mixture contains a single polymer and non-polymeric organic components at >10%:
        - The test material and polymer requires its own test; or
        - The test material can be tested as a whole as long as you can prove each of the polymers passes the criteria of the test carried out

Paragraph 15 requires manufacturers, importers and industrial downstream users claiming that certain polymers in their products do not meet the definition of SPM on grounds of degradability or solubility to provide proof proving those properties to competent authorities upon their request, without delay

3.4.2 Examples

Examples include polylactic acid (PLA), polylactic-co-glycolic Acid (PLGA).

3.4.3 Data Requirements:

The test methodologies permitted have been grouped together based on their ultimate endpoint. There are 5 groups in total. If performing tests from groups 4 and 5, the polymer must pass a test in each of the 3 compartments to be considered out of scope.

- Polymers that meet pass criteria using test guidelines and conditions specified within the text of the restriction – see Appendix 15
- Each methodology has been placed in a group – groups 1 to 5.
    - For groups 1-3, a pass in one test is sufficient to place a polymer outside the scope of the ban.
    - For groups 4 and 5 biodegradability needs to be proven in three different compartments.

The table below lists the permitted test methods, their groups, and pass criteria.

Table 5: Test methods permitted

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Group #	Permitted test methods	Test duration	Pass criteria	# tests required to be out of scope
1	OECD 301B OECD 301C OECD 301D OECD 301F OECD 310	28d	60%	1
2	OECD 301B OECD 301C OECD 301D OECD 301F OECD 310 OECD 306	28 – 60d	60%	1
3	OECD 302C	14d	≥70%	1
4	EN ISO 14852:2021 EN ISO 14851:2019 EN ISO 19679:2020 EN ISO 18830:2016 EN ISO 17556:2019 ISO 22404:2019	1. Aquatic – 6mo 2. Soil – 24mo 3. Sediment – 24mo, or; Water/sediment – 24mo	≥90%	3 – one from each compartment
5	OECD 307 OECD 308 OECD 309	1. Water – <60d 2. Sediment – <180d 3. Soil <180d	Degradation half life	3 – one from each compartment

Note: this table is a summary only. For full details on specific test conditions, please refer to the legal text

3.5 Use of read-across data in biodegradation and solubility studies

The regulation and EC guidance documents emphasize that it is necessary to use a test material that is comparable in terms of composition, form, size and surface area to the polymer particles, i.e. the particles containing or coated by solid polymer(s), present in the product as placed on the market or, if not possible, the polymer particles disposed of or released to the environment. This implies that a representative sample can be used for testing and can represent multiple grades of the polymer.

However, there are two exceptions to the above rule. The first concerns polymer particles that, when placed on the market, disposed of or released, have all dimensions greater than 0.25 mm or are longer than 0.25 mm and have a length to diameter ratio greater than 3. The OECD Guideline 120 requires that, before performing the test, these particles are milled so that at least one dimension, or their length, measures between 0.125 mm and 0.25 mm. The milling is necessary to ensure standardised, reproducible results and does not affect the conclusions that can be drawn from the test. The condition of the test and the pass criterion are sufficiently

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strict that a polymer that passes the test is regarded as soluble for the purpose of Entry 78, regardless of whether the test was performed on milled or intact particles.

The second exception concerns testing the solubility of polymer particles that, in addition to containing or being coated by solid polymers, also contain or are coated by inorganic substances. The presence of inorganic substances in the tested particle is likely to confound the result of the test. For this reason, when the particle also contains or is coated by inorganic substances, it is necessary to test the solubility of the individual polymer(s) rather than that of the polymer particle as placed on the market, disposed of or released.

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4 MEDICINAL PRODUCTS AND DEROGATION

Medicinal products for human and veterinary use are **exempt from the prohibition** on placing SPM on the market under Paragraph 1, as per **Paragraph 4(b)** of Entry 78. Excipients in medicinal products are considered intentional and confer a sought-after characteristic*, which would normally trigger the restriction. However, due to the derogation, such medicinal products are allowed on the market but must comply with reporting obligations.

This derogation applies to medicinal products within the scope of Directive (EC) 2001/83 and Regulation (EU) 2019/6[9]. The derogation **does not apply** to pharmaceutical ingredients that are not yet included in finished medicinal products. These will still qualify under **Paragraph 4(a)** if used at industrial sites

Example of sought-after characteristics in medicinal products:

- Binders
- Fillers
- Diluents
- Lubricants
- Disintegrants

Coatings in solid oral dosage forms (e.g., tablets)

Key Points:

- Scope: Applies to products under Directive 2001/83/EC and Regulation (EU) 2019/6. A correcting act is planned to include clinical trial products explicitly.
- No IFUD Requirement: These products are not subject to Instructions for Use and Disposal (IFUD) obligations
- Reporting Requirement: Suppliers must report estimated emissions under Paragraph 12 starting 31 May 2027
- Derogations that apply to medicinal products include the following:
- SPM used at industrial sites.

Paragraph 4 (a) of the restriction allows use of excipients that meet the definition of microparticles for use at industrial sites. Medicinal products used in clinical trials are also out of scope, there is a footnote added to Page 33 of Q&A Part 1 where it describes a Correcting Act to change the wording of paragraph (4b) to include medicinal drug products used in clinical trials in this derogation.

Paragraph 5 Derogations

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The Restriction aims to cover SPM that may enter the environment. This derogation addresses scenarios when the finished product as placed on the market contains SPM, but they are permanently modified during consumer use e.g. digestion-modified SPM. For medicinal products, this derogation is important as it impacts the reported quantity of SPM released into the environment. There are derogations for 3 different scenarios listed in the Annex to the Restriction:

- Paragraph 5(a) of the Restriction. SPM where there is no release into the environment during use because they are contained by technical means. May apply to devices (cartridges, feminine care products). swellable SPM contained in diapers may fall under Paragraph 5(a).
- Paragraph 5(b) of the Restriction - SPM where physical properties are permanently modified during consumer end use. Swellable polymers derogated under Paragraph 5 are subject to IFUD (Paragraph 8) and reporting requirements (Paragraph 12). Swellable polymers that form gels in the presence of water (or other **solvent**s) that do not contain particles do not fulfil the SPM definition.
- Paragraph 5(c) of the Restriction. SPM that are permanently incorporated into a solid matrix at the time of use.

Paragraphs 4(b) and 5(b) would apply to medicines containing e.g. film-forming or swellable polymers that are permanently modified during formulation and/or use.

The EC guidance notes that, "*If the polymers stopped being SPM at any point during digestion, they should not be reported*." This means that if a tablet's SPM content is chemically or physically altered during digestion such that it no longer meets the SPM definition, it is not subject to reporting. However, if the SPM remains intact and is excreted in similar form, it must be reported. Test methodologies to demonstrate physical properties of the SPM have been permanently modified are not listed in the Restriction.

Examples

- Coated (soluble) or uncoated modified release tablet > 5mm but containing carbomer: synthetic, swells in water and loses its particulate nature. The carbomer would not be an SPM as it changes particulate form during digestion.
- Coated (soluble) or uncoated immediate release tablet > 5mm but containing sodium starch glycolate as a disintegrant; semisynthetic synthetic, insoluble but swells in water with particle size (d_{90}) < 1 mm. This would remain an SPM after release.

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- Oral suspension containing polycarbophil as an auxiliary suspending agent; synthetic insoluble but swells in water. Loses its particulate nature and will not be an SPM on release after digestion.
- Tablet containing membrane-controlled modified release coated spheroids (< 1mm) coated with e.g. ethyl cellulose (semi-synthetic, insoluble in water) or polymethacrylate (synthetic, insoluble in water); membrane passes out of the body intact and will be considered SPM after release.
- Hard gel capsule containing membrane-controlled modified release coated spheroids (< 1mm) or minitablets (< 5mm) coated with e.g. ethyl cellulose (semi-synthetic, insoluble in water) or polymethacrylate (synthetic, insoluble in water); pass out of the body intact. The coated spheroid will be considered microparticle after release.
- Coated tablet > 5mm, coated with water insoluble polymer to provide modified release – not SPM.

Data Requirements

Test methodologies to demonstrate physical properties of the SPM have been permanently modified are not listed in the Restriction. There are no standard tests to demonstrate compliance with Paragraph 5(a), (b) or (c). The most suitable method depends on the type of SPM and its conditions of use; hence, specific methods cannot be recommended. Justification may not necessarily need to rely on analytical testing results but can be based on other credible scientific rationale and appropriate documentation. It is advised to thoroughly document and retain justifications for at least a period of 10 years in accordance with Article 36 of the REACH Regulation.

It is recommended that suppliers placing SPM derogated under Paragraph 5 on the market have sufficient scientific rationale/evidence available that the conditions of the derogation are met during the intended end use. It is for national enforcement authorities to decide whether the information provided by the supplier is sufficient to prove compliance.

For Pharma consideration: *in vitro* methods may be considered to assess the effect of the GI contents on the dosage form to develop justification for whether it is still an SPM.

Derogation for placing SPM on the market for R&D

The use of SPM for research and development purposes (e.g. chemical-grade reagents) is either not in the scope of the restriction or is derogated, depending on the type of research:

The use of SPM for **scientific research & development** (i.e. any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than

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one tonne per year according to Article 3(23) REACH) is out of the scope of the restriction: in accordance with Article 67 REACH, restrictions in Annex XVII REACH do not apply to the manufacture, placing on the market or use of a substance in scientific research and development (Art. 67 REACH).

For the purpose of the microparticles restriction Entry 78, the use of SPM for **product and process orientated research & development** is overall derogated under Paragraph 4(a), as it is a use of SPMs that usually takes place at industrial sites. In this case, IFUD and reporting obligations apply, in accordance with Paragraph 7 and 11, respectively[10].

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5 INFORMATION REQUIREMENTS FOR SUPPLIERS FOR SPM

Excipient manufacturers will need to provide mandatory instructions for use and disposal (IFUD) that explain to industrial downstream users and end users (professionals and the public) how the SPM or the product containing them should be used, handled and disposed of so that SPM releases to the environment are avoided or minimized. The term **"downstream user"** is defined in Article 3(13) of REACH as individuals or companies (other than the manufacturer or the importer) established within the EU/EEA who utilize substances or mixtures in their industrial or professional activities. Distributors or consumers are not downstream users according to that definition.

From 17 October 2025, manufacturers of SPM are required to provide the following:

- Instruction for use and disposal for industrial downstream user explaining how to avoid releases into the environment
- SPM statement
- The quantity or concentration of SPM
- Generic identity details required to comply with reporting requirements

Table 6: Party responsible for provision of information

Data Elements	Excipient Manufacturer	Excipient User
Supplier obligation (Oct 17, 2025)		
• use and disposal information	X	
• statement related to regulation	X	
• quantity of SPM	X	
• generic information on identity of polymer	X	

5.1 Key Points:

- The IFUD are mandatory for SPM, and products containing them, derogated under Paragraph 4(a), 4(d), 4(e), 5(a), 5(b) and 5(c). The excipient manufacturer will need to provide IFUD consistent with derogation under 4(a). The IFUD provided by manufacturers of SPM **for use at industrial sites** should be targeted to industrial downstream users and should explain how the SPM (and the product containing them) should be used, handled, stored and disposed of in an industrial setting.

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- Information can be provided on the SDS, primary or secondary packaging, or leaflet
    - Ingredients suppliers will provide the following generic data:
        - Name
        - EC Number or number assigned by ECHA
        - CAS Name
        - CAS number
- Manufacturers of SPM need to provide Instructions for Use and Disposal (IFUD). This does not apply to medicinal products incorporating SPM.
- The purpose of the IFUD is to prevent the release of unmodified particles into the environment.

6 REPORTING REQUIREMENTS FOR EXCIPIENT MANUFACTURERS AND USERS

Only primary SPM, i.e. SPM created and/or added to the product as such, or otherwise intentionally used, should be reported, including when generated from removal of the product. Secondary SPM, or unintentional SPM, for example by products and unintentional contaminants are not subject to SPM restrictions.

Reporting to ECHA is mandatory annually and must be submitted by 31 May each year. Multiple derogations can apply to the placing on the market of the same SPM. The placing on the market of SPM for use at industrial sites is always derogated under Paragraph 4(a). However, the placing on the market of the same SPM can also be derogated, at the same time, under Paragraph 5(b) if the use at the industrial site is the end use of the SPM (or the product containing them), and the SPM stops being SPM during that end use.

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Figure 6: Specific Reporting Obligations

in addition, all entities in the **supply chain** have the responsibility to report release to the environment during transportation if this occurs while they are responsible for the product.

Excreting the medicinal product is considered part of its intended end use. After the medicinal product and its metabolites are excreted from the body, and reporting has taken place, there are no further obligations under the restriction. See also Q&A 10.2 above.

If the change in form during digestion was simply to a fragmented or 'broken' version of the initially ingested SPM with comparable composition, and the broken polymers remain SPM at all times, then the excreted SPM should be considered to be within the scope of the restriction and subject to the reporting obligation. If the polymers stopped being SPM at any point during digestion, they should not be reported. Reporting of emissions at end use should be done by the first supplier placing the medicinal product on the market for professional/consumer use, not by the end-user, in accordance with Paragraph 12 of the restriction.

The data that needs to be provided depends on the derogation you are using for your product as summarized in table below:

Table 7: Information from EC guidance

Derogation Paragraph	Description	First reporting deadline	Data required for submission
4(a)	Placing on the market of SPM as substances or mixtures for use at industrial sites	31 May 2027	Applies to excipient manufacturers when production is conducted in the EU: • Uses of SPM in previous calendar year • Generic information on identity • For each use estimate of releases to the environment (including transportation) Reference to 4(a) derogation
4(b)	Medicinal products	31 May 2027	• Uses of SPM in previous calendar year • Generic information on identity

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			• For each use estimate of releases to the environment (including transportation) Reference to 4(a) derogation
5(a)	SPM contained by technical means	31 May 2027	• Description of end uses • Generic information on identity • Estimate of releases for each end use Reference to applicable derogation
5(b)	SPM physical properties permanently modified in use		
5(c)	SPM is permanently incorporated into a solid matrix (may not apply to medicinal products)		

The general principles for who should report, and which estimated SPM emissions should be reported, are the following:

A. For Manufacturers and Industrial Downstream Users (Paragraph 11)

- **Annual reporting** to ECHA of:
    - Description of the use(s) of SPM in the previous calendar year
    - Generic information on the identity of the polymers used
    - Estimate of the quantity of SPM released to the environment in the previous calendar year (including emissions during use and transport)
    - For each use, the applicable derogation(s) in Paragraphs 4 or 5

B. For Importers (Paragraph 12)

- **Annual reporting** to ECHA of:
    - Their own SPM emissions (including during transport)
    - Downstream SPM emissions (from the moment the product is placed on the market to the moment it is disposed of after end use)
    - Description of the use(s) of SPM
    - Generic information on the identity of the polymers used
    - For each use, the applicable derogation(s) in Paragraphs 4 or 5
- In the case of Paragraph 12, in order to ensure that all emissions along the supply chain are monitored and reported, without risking double reporting or adding undue burden on end users, the suppliers (manufacturers, importers, downstream users, as

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appropriate) of products containing derogated SPM that place those products on the market **for the first time to professional users or the general public** have to estimate and report:

  - their own SPM emissions, including during transport (even when performed by third-party transporter(s));
  - the downstream SPM emissions, i.e. the emissions occurring downstream in the supply chain all the way to the end user, from the moment the product is placed on the market to professional users and the general public to the moment it is disposed of after end use. These can be sector-specific release estimates, such as those described by spERCs.

- Importers of SPM, and of products containing SPM, that are derogated because they are placed on the market for use at industrial sites are not required to report their own estimated SPM emissions, in accordance with Paragraph 11;
- By contrast, importers of derogated SPM, and of products containing derogated SPM that place those products on the market for the first time to professional users and the general public are required to report their own estimated SPM emissions, including during transport, plus the estimated downstream SPM emissions, in accordance with Paragraph 12.
- When importers of products containing SPM estimate and report their own SPM emissions, they should estimate emissions generated once the product containing SPM enters the custom territory of the Union.
- Distributors, including retailers, of products for professional use and the general public, professional end users and consumers do not report SPM emissions to ECHA, even if they undertake further formulation – e.g. mixing of custom paint colours. This is because distributors (including retailers), by definition, receive the product from a third party, so when the distributor receives it, the product has already been placed on the market. It is the industrial actor placing the product on the market for the first time to professionals or the general public that has to comply with the reporting requirement.
- Products containing SPM, which are directly exported and not placed on market, are not subject to the reporting requirements.
  - What is the reporting requirement for products produced outside of the EU?

Any product imported into the EU must comply with the applicable EU legislation, including Entry 78 of Annex XVII to REACH. Reporting is obligatory for SPM derogated under Paragraphs 4(a), 4(b), 4(d), 4(e), 5(a), 5(b) or 5(c).

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Importers that have to estimate and report SPM emissions in accordance with Paragraph 12 should estimate emissions generated as of the moment the SPM or product containing them enters the custom territory of the Union.

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7 PROVISION OF ADDITIONAL SPM IDENTIFIERS TO ENFORCING AUTHORITIES (Paragraph 13 and 14)

- ECHA will provide all data submitted in line with Paragraphs 11 and 12 to national authorities.
- National authorities will be responsible for enforcement of the Restriction within its own country
- National regulatory authorities can request additional SPM identifiers, in addition to what has been provided in accordance with paragraphs 11 and 12, of any SPM placed on the market at any point in the supply chain during yearly reporting.

7.1 Key Points:

- Available information must be provided to the regulatory authorities within 30 days of receiving the request.
- In case requested information is not available, request must be forwarded upstream to the supplier within 7 days, and in parallel, the competent authority must be informed of this.
- When the data request is received by a downstream user, the SPM manufacturer can provide data to the downstream user or directly to the regulatory authorities
- Information related to polymer identity; justification of any derogation and other relevant information may be requested by the enforcing national authority. This will depend on the enforcing authority and the specific information being sought.

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8 PARAGRAPH 15 – DEMONSTRATION OF COMPLIANCE WITH EXEMPTION CRITERIA

- Where SPM fall out of scope of this restriction due to their biodegradability or solubility, regulatory authorities can request supporting reports.
- Data must be provided without undue delay.

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9 REFERENCES

[1] REACH Annex XVII, Entry 78 as introduced by Commission Regulation (EU) 2023/2055
[2] International Pharmaceutical Council General Glossary of Terms and Acronyms
[3] EC Q&A Reach Restriction of SPM EC 2023/2055 Explanatory Guide Part II Ver 1 2025 Q 6.8
[4] Define reference second reference for derogation under 4(a) from Introduction
[5] EC guidance document, Part I Section 2 (from 2.1.1.1)
[6] EC Q&A Reach Restriction of SPM EC 2023/2055 Explanatory Guide Part I Ver 1 2025 Pg16
[7] ECHA guidance on monomers and polymers, Chapter 3.2.1.3 https://echa.europa.eu/documents/1016 2/23036412/polym ers_en.pdf/9a74545 f-05be-4e10-8555-4d7cf051bbed
[8] EC 1907/2006 Annex XVII Entry 78, Appendix 15
[9] EC 1907/2006 Annex XVII Entry 78, Appendix 16

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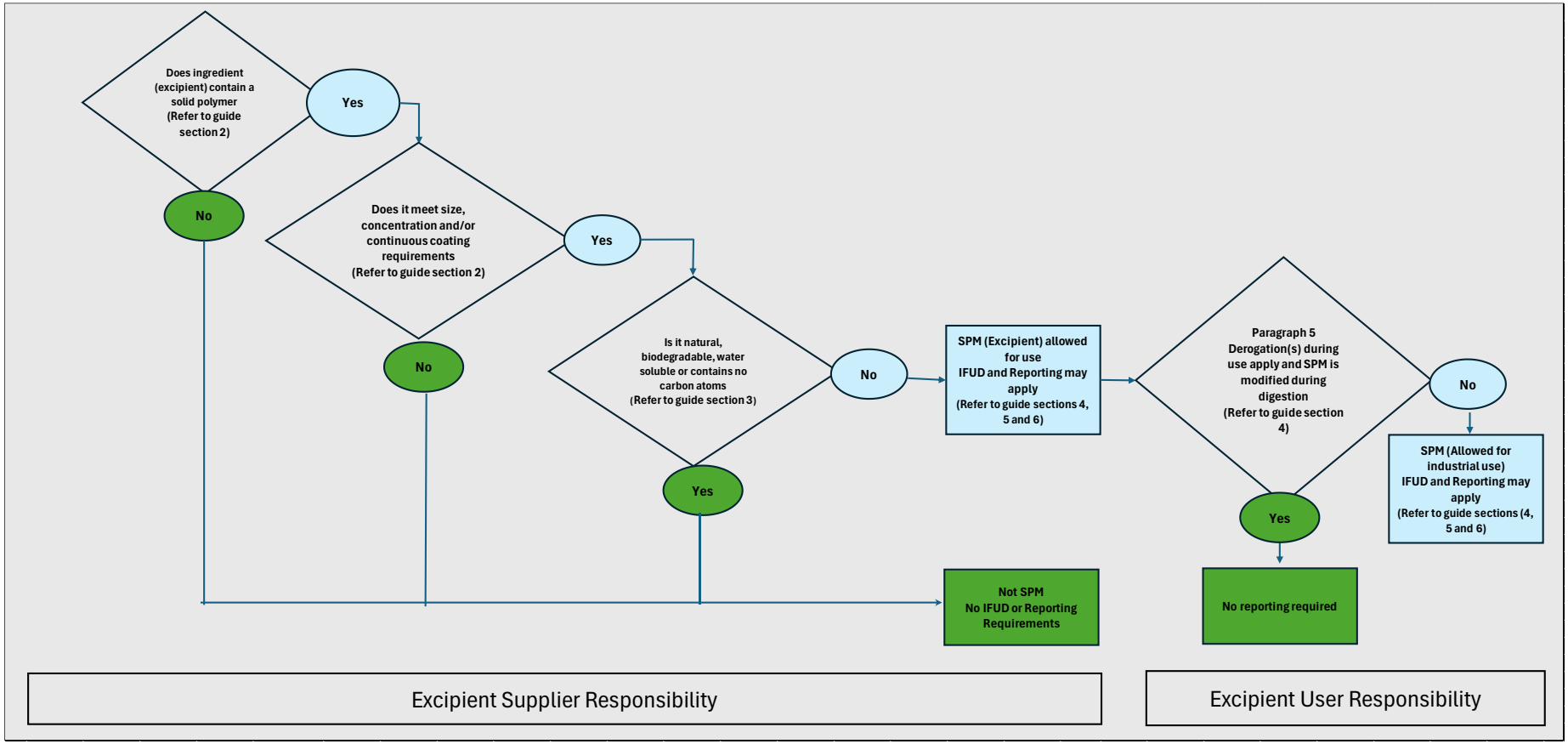
ANNEX 1

Assessment of Excipients for Use in Medicinal Products



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ANNEX 2
Link to legal text

Please see below the link to the official legal text:

https://eur-lex.europa.eu/eli/reg/2023/2055/oj

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ANNEX 3
Definitions and Abbreviations

Descriptor	Definition	Source
Actor in the supply chain	All manufacturers and/or importers and/or downstream users in a supply chain;	**Commission Regulation (EC) 1907/2006** EU REACH Article 3
Downstream user	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of "Downstream user"
Gas	A substance or mixture which at 50 °C has a vapour pressure greater than 300 kPa (absolute), or is completely gaseous at 20 °C at a standard pressure of 101,3 kPa;	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Paragraph 2(c)
Instructions for use and disposal	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of "substances occurring in nature"
Liquid	A substance or mixture that meets any of the following conditions: (i) the substance or mixture at 50 °C has a vapour pressure of not more than 300 kPa, is not completely gaseous at 20 °C and at a standard pressure of 101,3 kPa, and has a melting point or initial melting point of 20 °C or less at a standard pressure of 101,3 kPa; (ii) the substance or mixture fulfils the criteria in the American Society for Testing and Materials (ASTM) D 4359-90 Standard Test Method for Determining Whether a Material Is a Liquid or a Solid;	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Paragraph 2(d)

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Descriptor	Definition	Source
	(iii) the substance or mixture passes the fluidity test (penetrometer test) described in chapter 2.3.4 of Part 2 of Annex A to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) concluded at Geneva on 30 September 1957	
Make-up product	Any substance or mixture intended to be placed in contact with specific external parts of the human body, namely the epidermis, eyebrows and eye lashes, with a view to, exclusively or mainly, changing their appearance;	Commission Regulation (EU) 2023/2055 Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Paragraph 2(e)
Microbead	Synthetic polymer microparticles for use as an abrasive, i.e. namely to exfoliate, polish or clean, mainly used in rinse-off cosmetic products or detergents	Commission Regulation (EU) 2023/2055 Annex XVII restriction on synthetic polymer microparticles under EU REACH Paragraph 21
Nanomaterial	A natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50% or more of these particles in the number-based size distribution fulfil at least one of the following conditions: a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm; c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm. In the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger	Commission Recommendation (2022/C 229/01) 10 June 2022 - the definition of nanomaterial

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Descriptor	Definition	Source
	than 100 µm need not be considered. However, a material with a specific surface area by volume of < 6 m2 /cm3 shall not be considered a nanomaterial. The following definitions apply in the context of the above: a) 'particle' means a minute piece of matter with defined physical boundaries; single molecules are not considered 'particles'; b) 'aggregate' means a particle comprising of strongly bound or fused particles; c) (c) 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.	
Natural polymer	Polymers that are the result of a polymerisation process that has taken place in nature, independently of the process through which they have been extracted and not chemically modified substances	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Entry 78
Natural	A naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of "substances occurring in nature"
Not chemically modified	A substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of "not chemically modified substance"
Particle	A minute piece of matter, other than single molecules, with defined physical boundaries	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Paragraph 2(a)

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Descriptor	Definition	Source
Placing on the market	means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of "placing on the market"
Polymer	A substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer;	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of "Polymer"
Solid	A substance or mixture other than a liquid or gas	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Paragraph 2(e)
Synthetic Polymer Microparticle	Polymers that are solid and which fulfil both of the following conditions: (a) are contained in particles and constitute at least 1% by weight of those particles; or build a continuous surface coating on particles; (b) at least 1% by weight of the particles referred to in point (a) fulfil either of the following conditions: (i) all dimensions of the particles are equal to or less than 5 mm; (ii) the length of the particles is equal to or less	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Entry 78

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Descriptor	Definition	Source
	than 15 mm and their length to diameter ratio is greater than 3.	

Abbreviations:
IFUD – Instructions for use and disposal
SPM – Synthetic polymer microparticle

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