REACH restriction of synthetic polymer microparticles

(Entry 78 of Annex XVII REACH, as introduced by Commission Regulation (EU) 2023/2055)

Explanatory Guide –

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Part III - Annexes

1. Annex 1 – Decision trees for synthetic polymer microparticle (SPM) identification

The decision trees below (Figures 1 to 5) present the key questions, arranged across three tiers, which need to be answered to identify if a product (a substance, a mixture or a combination of a substance/mixture and an article) placed on the market contains SPM and would therefore be subject to the restriction in entry 78 of Annex XVII of REACH. Figure 1 shows the general decision tree to be followed. This is complemented by specific decision tree for Tiers 1a (Figure 2), 1b (Figure 3), 2 (Figure 4) and 3 (Figure 5). It may not be necessary to use all three tiers to conclude that a substance or mixture is not a SPM.

It is advised to start with simple checks, such as for the presence of polymers, and in particular solid polymer particles, in the substance or mixture placed on the market. The absence of either solid polymers or particles, or the presence of solid polymer particles below the proposed concentration limit of 0.01% w/w, will lead to a conclusion that the substance or mixture will not be affected by entry 78.

Note that both Tier 1a and 1b have to be fulfilled to progress to Tier 2, and their fulfilment can be assessed independently. In some cases, e.g. when information is available on a label or via the supply chain or other prior knowledge, it may be easier to start with Tier 1b rather than 1a.

At any step in the decision tree, if the answers to the questions lead to the conclusion that there is "no SPM in the substance or in the mixture placed on the market" (as indicated in the green oval shapes), then no further assessment is needed, and entry 78 does not apply to the SPM or mixture placed on the market. For example, if Tier 1a is not met there is no need to assess Tier 1b, and vice-versa.

Additional decision trees are included in Annex 2. They can assist in concluding whether the SPM use is derogated and subject to 'reporting' and 'IFUD' requirements.

Figure 1. SPM identification; General decision tree.

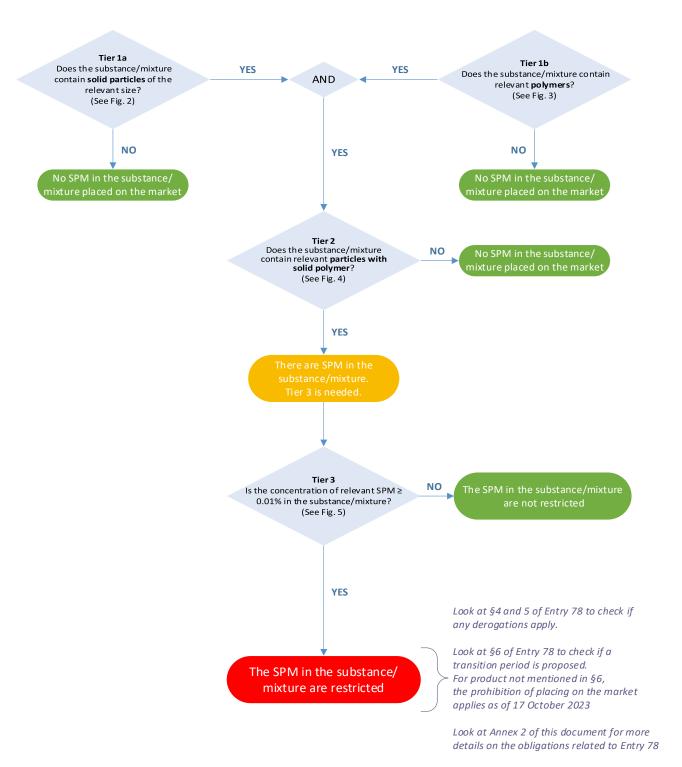


Figure 2. SPM identification; Tier 1a – solid particles of the appropriate size.

The lower particle sizes included in the flowchart below correspond to the temporary lower size limits set by Paragraph 3 of the restriction. These lower size limits apply when the compliance with the concentration limit referred to in Paragraph 1 cannot be verified with available analytical methods or the documentation accompanying the product for particles measuring $< 0.1 \mu m$ in any dimension (or $< 0.3 \mu m$ in length, if length/diameter ratio > 3).

'Solid' according to paragraph 2b of Entry Single molecules are not particles. Does the substance/mixture NO placed on the market contain solid Tip: Some techniques particles? to detect solid particles: - Visual check No solid particles in the substance/mixture. - Sieving / filtering No further assessment necessary. - Dynamic Light Scattering (DLS) YES Tip: Techniques to check particle size Do ≥1% (w/w) of the distribution: solid particles have all dimensions in YES - Sieving and weighing the size range Particle size 0.1 µm to 5 mm? distribution NO Particle size (mm) Do ≥1% (w/w) of the Tip: A quick way to solid particles have a length check this would be to between 0.3 µm to 15 mm, measure the mass included, and a length to proportion of solid diameter ratio >3? particles larger than 5 mm. If the mass proportion of particles larger than 5 mm is ≥ NO 99%, then there is no SPM in the substance/ mixture placed on the market. The solid particles do not fulfill the size criteria, therefore the polymers contained in/coating those particles are not considered SPM.

No further assessment necessary.

Tier 1a: Does the substance/mixture placed on the market contain solid particles of the relevant size?

Figure 3. SPM identification; Tier 1b – relevant polymers.

Tier 1b: Does the substance/mixture placed on the market contain relevant polymer(s)?

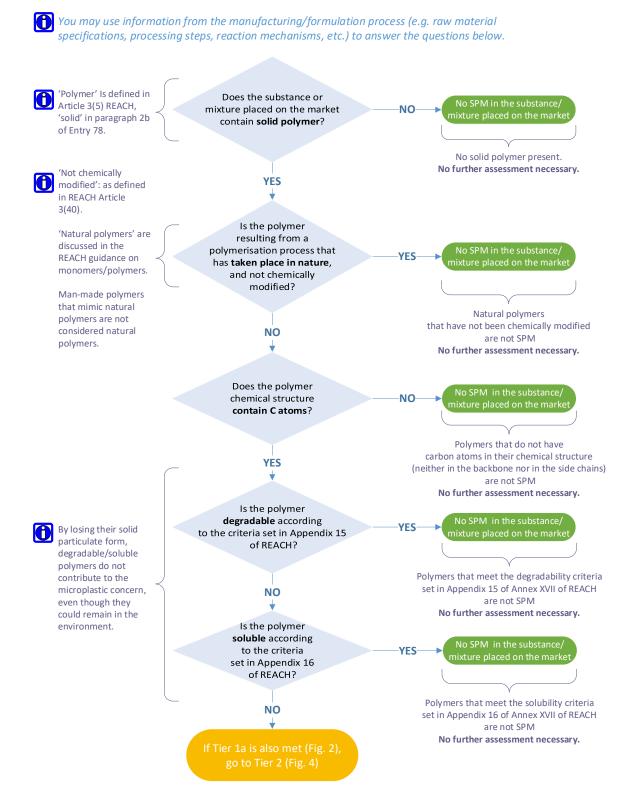


Figure 4. SPM identification; Tier 2 – relevant polymer-containing particles.

Tier 2: Does the substance/mixture placed on the market contain relevant particles containing or coated by solid polymer?

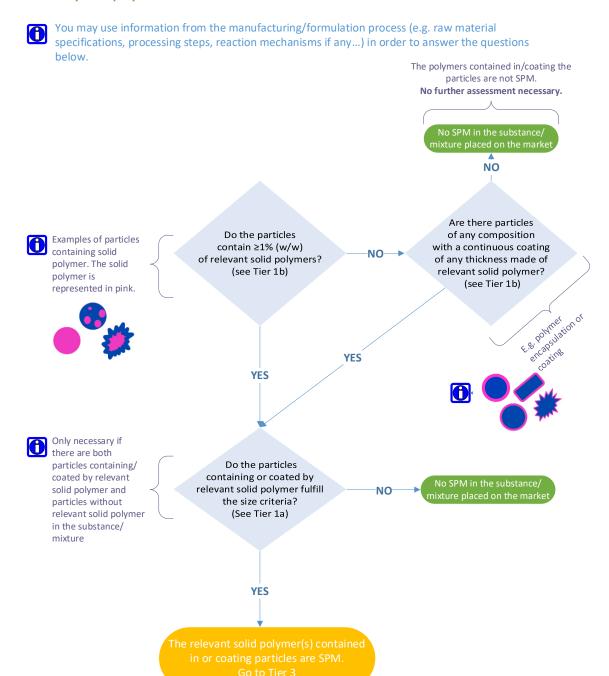
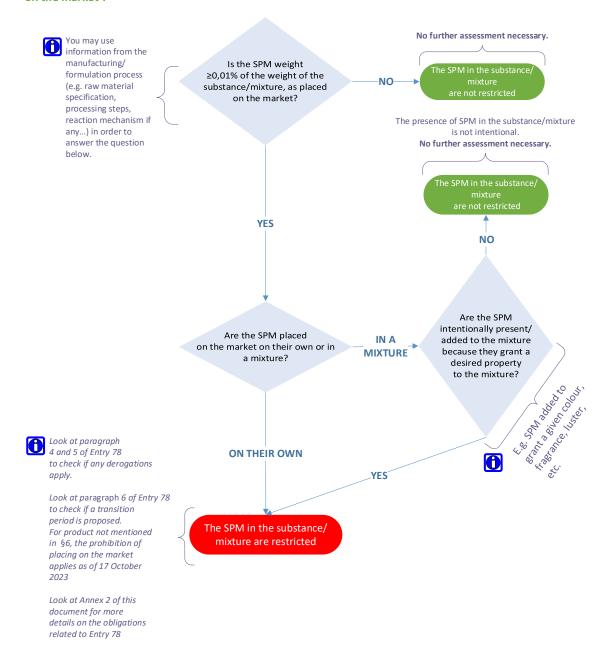


Figure 5. Tier 3 – concentration considerations and intentionality

Tier 3: Does the prohibition of placing on the market apply to the SPM in the substance/mixture, as placed on the market ?



2. Annex 2 – Obligations arising from entry 78 at different levels of the supply chain

The boxes below outline the obligations for suppliers (manufacturers, importers, distributors and downstream users, as defined in Article 3 of REACH), and downstream users at industrial sites, that arise from entry 78 when they place on the market or use a substance or mixture containing SPM.

How to read these diagrams?

Each grey box represents an actor/role in the supply chain, and includes the questions the actors/roles should ask themselves to identify their obligations under entry 78:

- Box 1 explains the obligations of an **EU manufacturer of a SPM**, or an **importer of SPM** (either on their own or in a mixture).
- Box 2 explains the obligations of **downstream users**^{1,2} **of SPM at industrial site**)
- Box 3 and 4 identify the different types of products, and the associated obligations of the importer or downstream user, when placing on the market SPM or mixtures containing SPM, **for the general public or professionals**. It identifies in particular the obligations of suppliers 'placing for the first time' SPM, or mixtures containing them, on the market for an end use allowed on the basis of Paragraphs 4(b), 4(d), 4(e), or 5.

The obligations (in terms of reporting, 'IFUD', placing on the market, etc.) of each actor in the supply chain are identified as orange, magenta or salmon-pink coloured shapes.

The red shapes indicate that the substance or mixture cannot be placed on the market after the entry into force of the restriction on 17 October 2023, or after the transitional period specified in Paragraph 6 of entry 78.

The green shapes indicate that the SPM are not restricted.

A company in the supply chain might have different roles under REACH: for example, a manufacturer (of the SPM) can also be a formulator (of the mixture to which the SPM are added), or a downstream user of the SPM they are manufacturing (for example: plastic

More information on downstream users and end-users is available here: https://echa.europa.eu/regulations/reach/downstream-users/about-downstream-users/who-is-a-downstream-user, or in ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R12: https://echa.europa.eu/documents/10162/2324909/r12_guidance_draft_for_committees_201507_en.pdf.

² Industrial downstream users are downstream users that <u>use</u> substances or mixtures at industrial sites. End-users are users that <u>use</u> substances or mixtures but do not supply them further downstream. Examples of end users include users of adhesives, coatings and inks, lubricants, cleaning agents, solvents and chemical reagents like bleaching products, etc. Producers of articles are end-users at industrial sites. Professional painters or consumers using paint are also end-users.

³ 'Placing on the market for the first time' means the first natural or legal person who supplies or makes available substances, mixtures or articles on the market in the EU. The first placing on the market in the EU will either be by the manufacturer or the importer of the substance, mixture or article concerned.

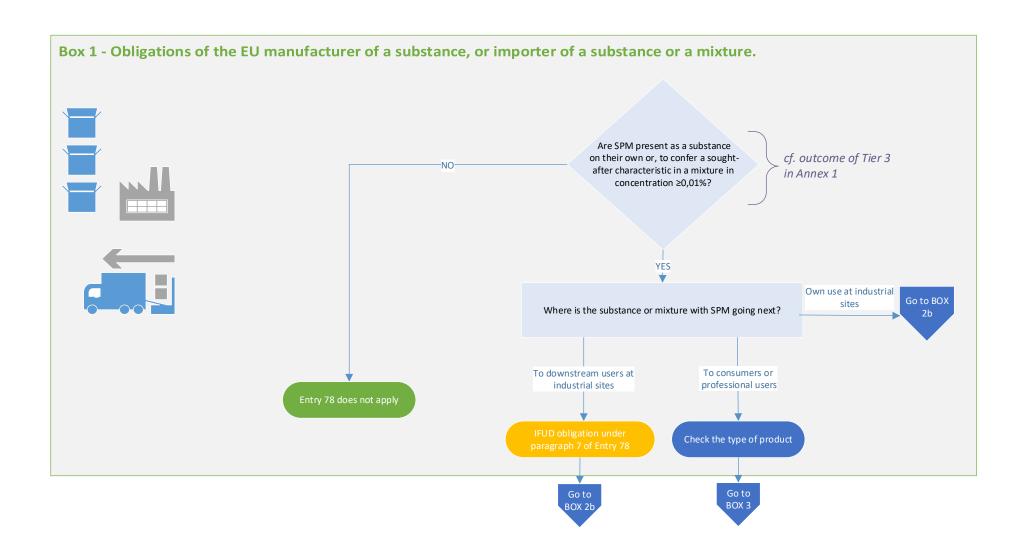
compounding for the production of plastic nurdles or pellets). In this case, the company will have to fulfil all obligations associated to the different roles.

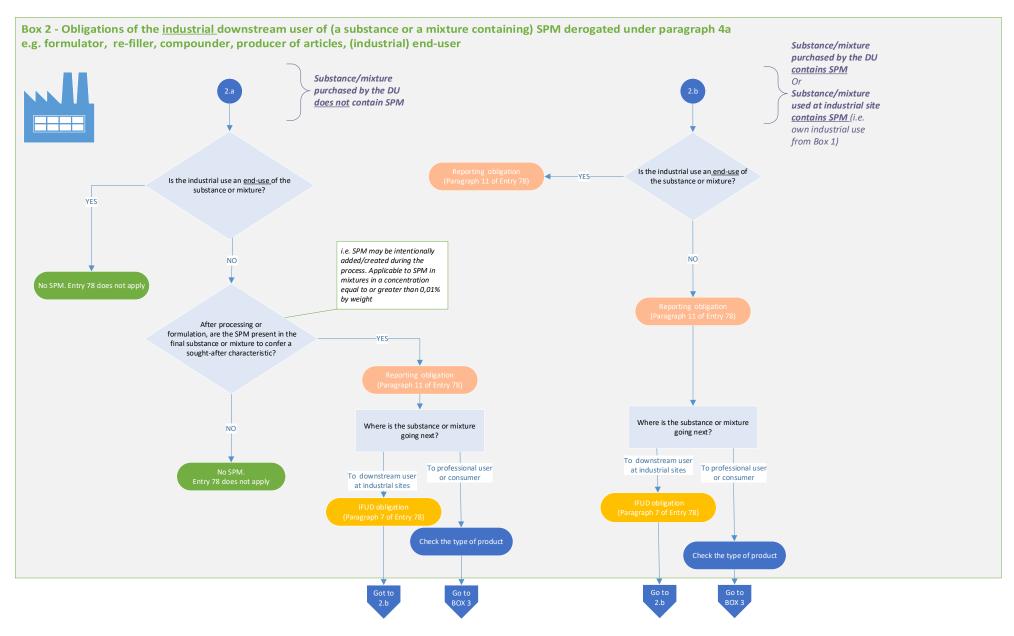
It should be kept in mind that 'use' is defined in REACH Article 3(24) as 'any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation'.

Distributors⁴ are not considered as downstream users. They have to comply with the information obligations in Paragraph 7 and 8 for SPM for which the placing on the market is derogated under Paragraphs 4(a), 4(d), 4(e) and 5 of the restriction and pass down the supply chain the relevant information necessary to enable appropriate use and disposal of the substance or mixture containing SPM.

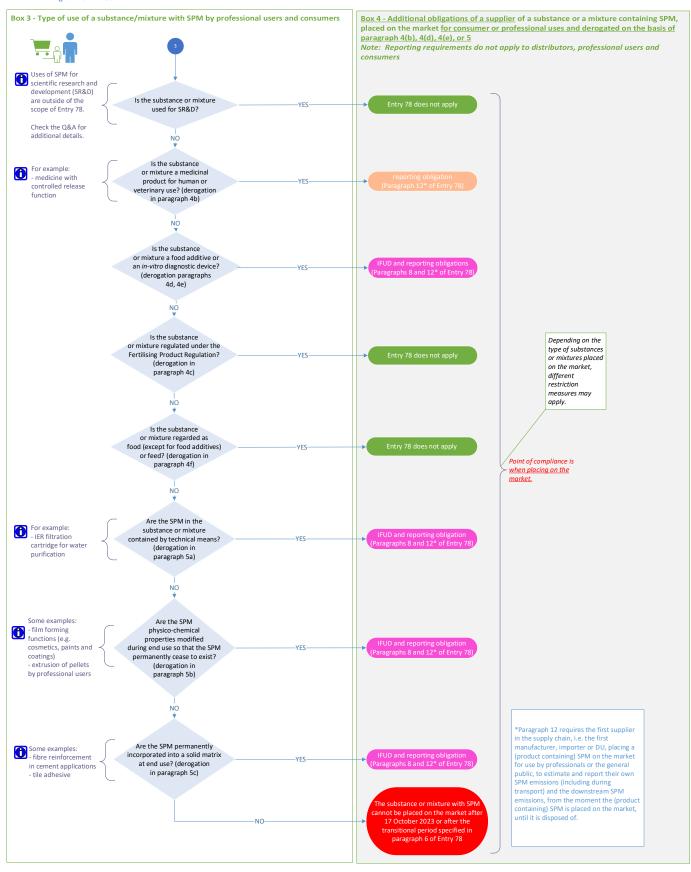
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⁴ Distributor: Actor who only stores and places on the market substances, on their own or in a mixture. This is not a downstream user according to REACH definition in Article 3(13) and (14).





Placing on the market:



3. Annex 3 – Borderline cases

This annex contains examples of borderline cases, i.e. where determining whether the product is a substance/mixture or an article is not straightforward.

Understanding whether a product is a substance/mixture or an article under REACH is important, among other things, because entry 78 only applies to SPM on their own or in mixtures.

The status (substance/mixture *vs* article) of borderline cases is assessed according to Chapter 2 of the <u>ECHA guidance on requirements for substances in articles</u>. Examples are added to this Annex after being assessed and agreed in accordance with that guidance.

In the following table, the product name and picture are presented with a description of the product, and an indication of whether the product is in or out of scope of the restriction or whether any derogations may apply.

The table is followed by three case studies showing detailed reasoning of whether a product is an mixture or an article according to the <u>ECHA guidance on requirements for substances in articles</u>.

3.1. Specific product examples

#	Product name*	Product description	In the scope/Out of the scope of the restriction
A3.1	Plastic beads for threading simonXT2 – Adobe Stock>	Used for threading necklaces, bracelets, etc.	Out of the scope. Plastic beads for threading are articles. The shape (including presence of a hole for threading) determines their function to a greater degree than does its chemical composition. Out of the scope.
A3.2	Glitter on its own (loose glitter) <amixstudio adobe="" stock="" –=""></amixstudio>	Shiny powder, flakes or needles, which may be used e.g. in toys, for art and crafts, and for decoration. Most glitter is made out of a combination of aluminium and PET but can also be made out of metal	In the scope. Glitter is to be considered a mixture and is in the scope of the restriction. Glitter is banned as of 17 October 2023, unless degradable, soluble, natural or inorganic, or derogated under Paragraphs 4, 5 or 16, or used for a use granted a transitional period under Paragraph 6. Glitter is not an article because the glitter composition (which

		or glass.	gives glitter its shine/colour) determines the glitter function (shining/colouring) to a greater degree than does its shape.
A3.3	Glitter affixed to an article ArtCookStudio – Adobe Stock> Africa Studio – Adobe Stock>		Out of the scope. When SPM-containing glitter (or another SPM-containing mixture) is affixed on the surface of an article, it is an integral part of the article (article with integral mixture). The same principle applies to flock printed material, e.g. on t-shirts.
A3.4	Sequins on their own New Africa – Adobe Stock>	Shiny, generally flat, disk-shaped ornaments, usually pierced with a hole for sewing them onto articles.	Out of the scope. Sequins are articles. The shape (including presence of a hole for threading, flatness) determines its function to a greater degree than does its chemical composition, regardless of size. (While the shine is important for their function, in this case it is considered secondary to their flat, pierced shape, which allows sequins to be sewn flat on articles). This is also applicable to pearls or other decorations intended to be threaded or sewn: they are outside the scope of the restriction.

A3.5	Sequins affixed to another article		Out of the scope. Article. Same as sequins on their own.
	<usama adobe="" stock="" –=""></usama>		
A3.6	Fake fur on plush/stuffed toys Oream Canvas – Adobe Stock>	Polymeric fibres 15 mm and less in length on soft-filled toys and on figurines covered with micro nylon fibres.	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.
A3.7	Ironing plastic beads (or "fuse beads")	Beads used to create permanent shapes by inserting them on a pegboard and then ironing them. The beads melt together to generate the wanted shape.	In the scope (mixtures). Derogated under Paragraphs 5(b) and 5(c). Since ironing plastic beads partly melt and lose their particulate form at end use, they are no longer SPM and are derogated under 5(b). In addition, the partly melted beads fuse with each other and form a solid matrix trapping the beads, so Paragraph 5(c) applies.
A3.8	Sticky beads (or "water fuse beads") <olga adobe="" stock="" u="" –=""></olga>	PVA beads that stick together when sprayed with water. No heat necessary. Can be used with or without pegboard. When sprayed, PVA beads partly dissolve and stick together when drying, generating the wanted article.	In the scope. Derogated under Paragraph 5(b). PVA beads are to be considered mixtures. Their composition (water-soluble PVA, no alternatives) determines their function to a greater degree than does their shape. They are in the scope of the proposed restriction if sized < 5mm. However, since they lose their particulate form at end use, they are no longer SPM and are derogated under 5(b).

	L	T	
A3.9	Glitter glues <storyteller63 adobe="" stock="" –=""></storyteller63>	Glue containing plastic glitter for art and craft and decoration. When used, the glue dries, permanently trapping the glitter inside the dried glue.	In the scope. Derogated under Paragraph 5(c) Glitter glues are to be considered as mixtures containing SPM (the polymer(s) in the glitter). They would be derogated on the basis of Paragraph 5(c).
A3.10	Modelling clay/putty	Dough-like compound containing polymeric beads and encapsulated pigments. Used to form shapes and objects. Some brands can be reused several times, but all tend to dry in the end (to keep the given shape).	In the scope. Derogated under Paragraph 5(c) Modelling clay/putty is to be considered a mixture. It may contain SPM (polymeric beads/glitter/encapsulated pigments). As the clay/putty permanently traps the SPM during end use (i.e. when the putty is set into a given shape), SPM would be derogated under Paragraph 5(c).
		The polymeric material may be provided separately (e.g. in a separate bag) from the dough-like compound.	
A3.11	Slime <katelin adobe="" stock="" –=""></katelin>	Slime typically consists of PVA + borate ions. When PVA reacts with the borate ions, it creates a thick, sticky "non-Newtonian" liquid.	Slime is to be considered a mixture. It typically consists of PVA + borate ions. PVA in slime is not solid, so it is out of the scope. Slime may contain SPM, e.g. polymers in glitter, encapsulated pigments, Styrofoam (polystyrene) beads. SPM in slime is not derogated under Paragraph 5(c), because slime cannot be considered "a solid matrix". Consequently, SPM in slime are banned as of 17 October 2023.

A3.12	"Magic sand" (also named "kinetic sand") <lithiumphoto adobe="" stock="" –=""></lithiumphoto>	Sand surrounded by a liquid polymeric substance. It is used like a modelling clay to form shapes. It can be re-used several times.	Out of the scope if the polymer coating the sand in the "magic sand" is liquid (and therefore is not a SPM). It may be in the scope of the restriction if the sand is coated by a polymer fulfilling the SPM conditions and at least 1% by weight of the coated sand particles measure equal or less than 5 mm in all dimensions. If the magic sand includes SPM (e.g. in case of SPM-coated sand), the SPM are not derogated under Paragraph 5(c), because magic sand cannot be considered "a solid matrix". Consequently, the placing on the market of SPM in magic sand is restricted as of 17 October 2023.
A3.13	Filling pellets and beads in soft-filled toys. < Adi / Stanislau_V – Adobe Stock>	Polymeric pellets and expanded polystyrene (EPS) filling beads are used for toy shape retention. They are entirely embedded into the toy and cannot be accessible for safety reasons (to prevent possible choking). Toy Safety Directive requires toy to pass tension test on seams and materials (EN 71-1).	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.
A3.14	Plastic gems Amir Barjric – Adobe Stock>	Standalone, shiny, faceted gems, used e.g. for art decorations.	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.

A3.15	Wax crayons	Paraffin wax crayons used for colouring. The wax chips throughout use.	Out of the scope. Paraffin wax crayons are not articles but mixtures of paraffin and pigments — see ECHA guidance on requirements for substances in articles. However, given that the paraffin in the crayon is not in particulate form, and the crayon is larger than 5 mm in at least one dimension, paraffin wax crayons can be regarded as out of scope.
A3.16	Diamond painting (painting with diamond-like beads) <yavdat adobe="" stock="" –=""></yavdat>	A mini rhinestone, diamond-like facet or faceted bead has usually less than 5 mm. They are commonly made from a polymeric resin (e.g. epoxy, acrylate, polyester) which undergoes curing or acrylic (co)polymer (thermoplastic). Dyes are added to the polymeric premixtures to provide the desired shades and hues.	Out of the scope. The diamond-shaped gems are articles. A specific shape is needed to perform the function. The shape is key to construct a uniform pattern of mini rhinestones on the painting canvas when making the painting. Therefore, the shape is more important to make the painting assembly than the chemical composition of the mini rhinestone. The product is therefore an article and articles are out of scope.
A3.18	Sequins without holes	Set of flat sequins without holes to stick on a self-adhesive backing to create a picture.	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.

A3.19	Stickers Generative Art- Adobe Stock>	Polymer/plastic sticker is a solid piece of plastic with a pressure sensitive adhesive coating/layer on one side.	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.
A3.20	Glitter gel pens <luke adobe="" stock="" –=""></luke>	Pens containing coloured gel inks mixed with polymeric glitter	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.
A3.21	Water beads for gel blasters OpenisNata – Adobe Stock>	Beads made of superabsorbent (swellable) polymers and used as ammunition for "gel blaster" guns	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.
A3.22	- Styrofoam beads - Slime containing Styrofoam beads - Playfoam < Pawel Michalowski – Adobe Stock>	Styrofoam beads or similar polymeric beads with a diameter <5 mm, often mixed with slime or other fluids (e.g. in Playfoam) for crafts projects.	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.

A3.23	<pre><realliia adobe="" stock="" –=""> Flock-coated products (flocked hangers, etc)</realliia></pre>	Articles (e.g., hangers, decorations etc.) with elements of flock (made of viscose, polyester, micro nylon)	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.
A3.24	Photo from William Cooke - WSP. Fake polyester grass coating	Decoration with effect (polyester) applied	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements
	<xmarynka adobe="" stock="" –=""></xmarynka>	to the surface of products	for substances in articles. The conclusions will be included here once available.
A3.25	Polyester Pom-pom Cliff – Adobe Stock>	Pom-pom made of polyester fibres	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.

A3.26	Snow globe Snow globe	Decorative object containing a mixture with polymeric artificial snow	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.
A3.27	Glittered candles <scovad adobe="" stock="" –=""> <attasit adobe="" stock="" –=""></attasit></scovad>	Candles where glitter is either inside the wax or is affixed to the external surface of the candle.	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.
A3.28	Bath Slime Nikolay – Adobe Stock> s All images in Apper 3 © Ado	Polymeric powder or small granules that can be added to bath water to turn it into "slime" in water	This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available.

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