European Polymer Dispersion and Latex Association

STATEMENT

December 2022

EPDLA's position paper on polymer dispersions, redispersible powders made thereof and nanomaterials

The EPDLA (European Polymer Dispersion and Latex Association, a Cefic Sector Group) is dedicated to promote the safe manufacture, transportation, distribution, handling and use of waterborne polymer dispersions and redispersible powders made thereof, in compliance with regulatory requirements and industry guidelines.

EPDLA members are committed to Responsible Care® principles and have implemented risk management according to the precautionary principles.

Polymer dispersions

Polymer dispersions are used as binders in many waterborne applications, e.g. adhesives, coatings and paints, carpets, non-woven, paper and paperboard coatings, plasters and textile finishing agents. Polymer dispersion technology has been used safely and successfully for more than 50 years and has contributed to a significant reduction in the release of organic solvents in the environment. Common to all dispersions covered by this paper is a film forming process during application.

Polymer dispersions are mixtures as defined under Article 3(2) of the REACH Regulation[1], consisting mainly of water and high molecular weight polymer droplets. The particle size of such polymer droplets can widely vary between ca. <100 nm (<0.1 µm) and 10,000 nm (10 µm) in diameter [2].

This makes the low end of the polymer particle size distribution fall into the domain of the nanomaterials definition, and this paper is meant to address user questions about safety and regulatory status of polymer dispersions from this specific nanomaterial point of view.

The polymer droplets are dispersed and stabilized in water and regarded as embedded in the liquid matrix**.** They cannot be isolated as discrete "droplets" by simple separation techniques and do not exist without their waterborne environment. Polymer dispersions are stable under the normal or advised storage, transport and handling conditions. By evaporation of the water a separation between the aqueous and the polymeric phase is enacted and leads to the film formation via coalescence of the polymer droplets (MFFT of the polymer is below room or ambient temperature). Coalescence is

[1] 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

[2] nm = nanometer / µm = micrometer

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the process where discrete droplets lose their identity[3](see Annex I), which is a property that e.g. isolated inorganic nanoparticles lack under ambient conditions.

The polymer droplets are formed by a polymerization reaction in liquid phase or by special emulsifying techniques that naturally generate a size distribution. The nano scaled polymer droplets (if present) are neither intentionally added to the water phase nor intended to be extracted or released from the polymer dispersion even during further processing. Commission Recommendation 3689(2022)[4] also states, that materials with a volume specific surface area less than 6 m^2/cm^3 should not be considered a nanomaterial. (A liquid like a polymer dispersion in delivery form has a specific surface of 6 cm^2/cm^3). The official review document[5] of the revised Commission recommendation on the definition of nanomaterials of 10.06.2022 (chap. 2.6.4) together with available JRC documents[6] (e.g. chap. 7.1.6.2) clearly turns out that polymer dispersions in the nano-size range can be regarded as non-particulate nanomaterials that are not in scope of the current EC recommendation. As already stated above, this is mainly attributed to the fact that the polymeric droplets and their aqueous environment depend on each other and make up a new material with new properties. Polymer Dispersions cannot be simply described as suspensions of polymeric particles in water.

Redispersible polymer powders

Redispersible polymer powders (RDP) are obtained through spray-drying of polymer dispersions with the help of a spray drying adjuvant polymer. Such spray drying adjuvant polymers are water soluble polymers. During spray drying larger particles in the micrometer range, typically >1 µm are formed as loose agglomerates of a few polymer dispersion droplets individually covered by the spray drying adjuvant polymer.

Due to their decisive influence on cement, lime or gypsum based finished drymix mortar products, as well as on cement free and mineral-binder free systems, they are mainly used as building material additives in construction-applications to provide e.g. adhesion to many types of surfaces and substrates or waterproofing.

The RDPs are usually free-flowing fine powders, with a particle-size distribution in the micrometer-range, which excludes them from falling under the nanomaterial definition. Moreover, the RDPs contain a sort of liquid core (the original Polymer droplets) in a shell of a dried water-soluble polymer. In contact with water, the RDP particles disappear as the soluble polymer dissolves and release the individual dispersion droplets in their original state again. This redispersed polymer powder has the same properties as the original polymer dispersion.

Polymer Dispersions with a particle-size distribution between 1-100 nm are differently stabilized compared to those stabilized by a soluble polymer, namely by emulsifiers. Spray-drying such polymer dispersions leads to polymer powders in the micrometer range, which are not redispersible.

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[3] (469) EPDLA Sector Group of Cefic - YouTube

[4] Commission Recommendation of 10.6.2022 on the definition of nanomaterial (C (2022) 3689)

[5] https://ec.europa.eu/environment/chemicals/nanotech/pdf/SWD_2022_150_2_EN_part1_v4.pdf

[6] https://publications.jrc.ec.europa.eu/repository/handle/JRC91377

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In summary: Redispersible polymer powders (RDP) will normally not fall under the nanomaterial definition.

Film forming process

On application, polymer dispersions and redispersed polymer powders are converted to a dry film, the properties of which usually determine the performance of the final product. The film forming process might be supported e.g. by film forming agents or elevated temperature if appropriate.

The film forming process can be divided in four phases (see Annex I)[3]:

1. The water evaporates and the polymer droplets close up in the diminishing liquid volume until the droplets form a dense packing.
2. Further evaporation of water results in high capillary forces, causing droplet attraction and filling of void space in between the polymer droplets.
3. The polymer droplets deform and converge to produce a continuous polymer-film[7] (see also phase III in Annex I to this paper)
4. Further fusion by inter-diffusion of macromolecules from adjacent droplets imparts mechanical strength.

Exposure to polymer dispersions

EPDLA recognizes that regulators, NGOs, the academic community as well as the media pay increased attention to the toxicological and environmental properties of nanomaterials.

The polymer droplets in polymer dispersions and redispersed polymer powders - including those at the nanoscale – are not individually available during recommended application conditions. In these systems the polymer droplet is formed in water and delivered as such, then coalescence takes place to form a (polymeric) film.

Consequently:

- The release of isolated nanoparticles, if present at all, from a polymer dispersion (or redispersed polymer powders) is not expected during film formation and can be excluded as a possibility for the final polymer film.
- All polymer droplets in a polymer dispersion do not exist without their waterborne environment; thus they are embedded in water.
- Individual droplets irreversibly lose their identity during the application process (film formation) and the polymer dispersion no longer exists. The smaller the polymer droplet size and the higher the specific surface the faster the film formation.

[7] „Untersuchung der Filmbildung aus Polymerdispersionen mit Hilfe der forcierten Rayleighstreuung“ –Dissertation Thilo Jahr, Johannes-Gutenberg University, Mainz (2002)

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- Materials with a volume specific surface area less than 6 m^2/cm^3 should not be considered a nanomaterial.

Any exposure of humans and the environment to polymer dispersion droplets cannot be totally excluded during production and processing. Polymer dispersions are stable under the normal or advised storage, transport and handling conditions and the release of isolated polymer droplets and consequently any human or environmental exposure to isolated droplets is not expected. Therefore no concerns due to nanoparticles in polymer dispersions are anticipated in the life cycle of polymer dispersions or in the application of polymer dispersion-based waterborne products, e.g. paints or adhesives, under advised conditions.

Nevertheless, workers should always refer to the corresponding Safety Data Sheet (Section 8 Exposure control/personal protection) before handling polymer dispersions or redispersible powders and apply the recommended safety measures, e.g. dust masks when spray drying or using gloves when open handling.
According to the amended Annex II of REACH (Regulation (EU) 2020/878) after evaluation of each product a phrase can be added in Section 1 of the SDS depending on the outcome:
'This mixture does not contain nanoforms' or 'This mixture contains nanoforms'. If the specific nanoform has an impact on the overall classification of the product, it will be mentioned separately in section 3 of the SDS.

Please refer to Annex II below for further information on risk evaluations.

- The present position paper has been developed by EPDLA members in good faith, to the best of its knowledge and following the latest scientific evidence.
- The position paper is offered to all EPDLA members for further use. Each producer might add additional information in the communications towards customers, depending on the specific situation.
- Normal or reasonable foreseeable conditions of use of a polymer dispersion product are defined by the respective producer for each specific product. Polymer dispersions should always be applied as recommended by the producer.
- EPDLA commits to update this document in view of any new relevant available information.

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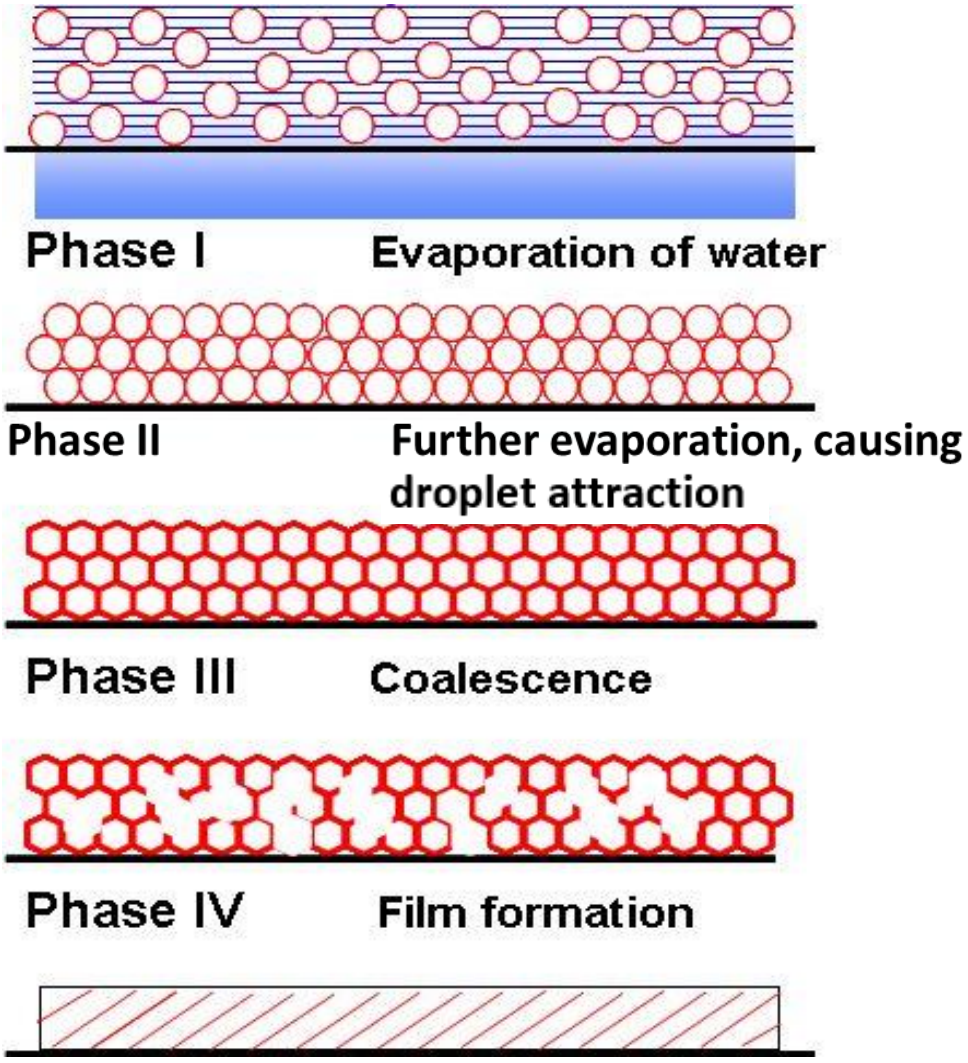
Annex I - Film forming process of polymer dispersions[8, 3]



[8] Compare M.A. Winnik, The Formation and Properties of Latex Films in Emulsion Polymerization and Emulsion Polymers, P.A. Lovell und M.S. El-Aasser (Eds.), Wiley, New York, S. 467 (1997).

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Annex II – Risk evaluations and consideration of waterborne Polymer Dispersions towards different nanomaterial definitions or regulations

Studies[9] have shown that the release of particles from paints depends greatly on the substrate and the paint itself, but not primarily on the fact that nanoparticles (e.g. from fillers and pigments) are incorporated. It was also shown that the release of paint particles with a diameter of less than 100 nm is negligible compared to the usual expected content of nanoscale particles in indoor and outdoor air. These findings were accordingly highlighted in a factsheet from the Umweltbundesamt[10]. These results should be transferable to polymer dispersions, given that they are the basis for such paints and waterborne mixtures. Therefore, the risk linked with exposure by inhalation to particles released by dispersions in the typical conversion settings is regarded as extremely low[11]. This concurs with the findings of the scientific study carried out in 2012 "Short-Term Rat Inhalation Study with Aerosols of Acrylic Ester-Based Polymer Dispersions Containing a Fraction of Nanoparticles" [12]. In this study, none of the tested preparations of acrylic ester polymers elicited any adverse effect at the end of the inhalation or post-inhalation periods. No negative shift in toxicity could be observed by an increased proportion of nano-sized polymer particles.
Investigations with a nanoparticle-containing acrylic copolymer dispersion showed no acute toxicity in fairy shrimps and zebra fish embryos (according UN GHS). In addition dietary studies in zebrafish showed that the particles are internalized, which was not associated with significant toxic effects[13].
The EU Scientific Committee on Consumer Products has addressed already dermal contact with Nanomaterials in the case of sunscreens, which are dispersions of solids in a liquid matrix. There is no evidence of a direct hazard if healthy skin is exposed to nanoparticles in the order of 20 nm or above from e.g. sunscreens[14]. Intensive, direct contact of polymer particles in dispersions with skin would be

[9] Göhler, D., Stintz, M., Hillemann, L., Vorbau, M. (2010): Characterization of nanoparticle release from surface coatings by the simulation of sanding process. Ann. Occup. Hyg., 54 (6), 615-624, 2010. http://annhyg.oxfordjournals.org/content/54/6/615.abstract

[10] https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/use_of_nanomaterials_in_coatings_0.pdf

[11] 10 Years of Research: Risk Assessment, Human and Environmental Toxicology of Nano-materials, Status paper issued by DECHEMA / VCI Working Group "Responsible Production and Use of Nano-Materials, October 2011; http://www.dechema.de/dechema_media/Downloads/Positionspapiere/Nanomaterials+Risk+Assessment.pdf)

[12] International Journal of Toxicology (2012, Volume 31, No 1, pp 46-57)

[13] Galloway, Tamara Dogra, Yuktee Garrett, Natalie Rowe, Darren Tyler, Charles Moger, J. Lammer, Eva Landsiedel, Robert Sauer, Ursula Scherer, Gertrud Wohlleben, Wendel Wiench, Karin. (2017). Ecotoxicological assessment of nanoparticle-containing acrylic copolymer dispersions in fairy shrimp and zebrafish embryos. Environ. Sci.: Nano. 4. 10.1039/C7EN00385D.

[14] Scientific Committee on Consumer Products SCCP Opinion on safety of Nanomaterials in Cosmetic Products from December 2007 http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf, p. 12 & 36

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an exception and not intended in most of the applications of polymer dispersions, so that this study might serve as a worst case. Finally, swallowing can be excluded as likely route of exposure.
In general, there is increasing scientific evidence regarding both human toxicity and potential environmental effects of nanomaterials which suggests no overarching statements can be made on nanomaterials per se, but that for nanoscale substances a risk assessment on a case-by-case basis is needed – like for all other substances. [15; 16; 17]

A study on Migration of Nanoparticles from Plastics into Foods has not shown any evidence that Nanoparticles would migrate from the LDPE host polymer into food simulants even under very severe test conditions.[18] We would expect the same findings for a migration experiment from a film obtained by drying a polymer dispersion, which e.g. originates from an adhesive used in food packaging.

Nevertheless workers should always refer to the corresponding Safety Data Sheet before handling polymer dispersions and apply the recommended safety measures, e.g. dust masks when spray drying or using gloves when open handling.

Risk Assessment according to recognized tools

EPDLA evaluated the potential risk from polymer dispersions and determined the risk classes for polymer dispersions applying two well-known scientific tools, namely

- *Stoffenmanager Nano Module* (Dutch tool) [19]
- *Développement d'un outil de gestion graduée des risques spécifique au cas des nanomatériaux*

[15] Donaldson, K and Poland, CA; Nanotoxicity: challenging the myth of nano-specific toxicity; Current Opinion in Biotechnology 2013, 24:724–734

[16] Krug, H.: "Nanosafety Research — Are We on the Right Track?"; Angewandte Chemie Intern. Ed., Special Issue: Nanotechnology & Nanomaterials, Nanotoxicology & Nanomedicine, Vol. 53, Issue 46, pp 12304–12319, Nov. 10, 2014, http://dx.doi.org/10.1002/anie.201403367

[17] Wagner, S., Gondikas, A., Neubauer, E., Hofmann, T. und Frank von der Kammer: „Spot the Difference: Engineered and Natural Nanoparticles in the Environment — Release, Behavior, and Fate"; Angew. Chemie Intern. Ed., Vol. 53, Issue 46, pp 12398–12419, Nov. 10, 2014, http://dx.doi.org/10.1002/anie.201405050

[18] Bott, J.; Störmer, A. Franz, R.: "A comprehensive study into the migration potential of nano silver particles from food contact polyolefins" Chemistry of Food, Food Supplements, and Food Contact Materials: From Production to Plate. Chapter 5, pp 51–70. (2014) *ACS Symposium Series*, Vol. 1159. Chapter DOI: 10.1021/bk-2014-1159.ch005 // Bott, J.; Störmer, A. Franz, R.: "Investigation into the migration of nanoparticles from plastic packaging materials containing carbon black into foodstuffs" Food Additiv. Contam. Vol. 31 (10) 1769-1782 (2014). DOI: 10.1080/19440049.2014.952786. // Bott, J.; Störmer, A. Franz, R.: "A model study into the migration potential of nanoparticles from plastics nanocomposites for food contact". Food Packaging and Shelf Life2 (2) 73-80 (2014). DOI: 10.1016/j.fpsl.2014.08.0001.

[19] http://nano.stoffenmanager.nl/Default.aspx

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- *(*Anses, French tool)[20]

In both cases polymer dispersions ended up in the lowest risk category.

This is confirmed by the fact that manufacturing and use of polymer dispersions is a well established and mature technology which has proven to be safe for decades, long before any discussion on nanomaterials was started.

European Union - Commission Recommendation, of 10.6.2022 on the definition of nanomaterial (2022/3689/EU)
Excerpt of the definition:
"'Nanomaterial' means 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;*
…..
However, a material with a specific surface area by volume of < 6 m2/cm3 shall not be considered a nanomaterial."

EPDLA Conclusion: Polymer dispersions and redispersed polymer powders are out of the scope of the EC Recommendation (**2022/3689/EU**). The polymer droplets are dispersed in water, embedded and stabilized in the liquid matrix. The existence of the waterborne environment is a prerequisite for the polymer droplets to exist. The dispersed phase wouldn't be stable without the other. Moreover during further processing the polymer particles will converge to form a continuous film or matrix.
The recommendation also clearly states that "The definition should exclude non-solid (i.e. liquid and gaseous) particles. This should ensure that the highly dynamic nature of the external dimensions of non-solid particles, such as micelles or nanoscale droplets in emulsions or sprays does not prevent the use of the external dimension as the defining qualifier in the definition."
Due to their particle size in the micrometer range, most redispersible polymer powders are out of the scope of the EC Recommendation (**2022/3689/EU**).

France - Ministerial Order on Annual declaration of substances with nanoparticle status, 06.08.2012
Excerpt of the definition:
"*Substance at nano scale": substance as defined in article 3 of EC regulation no. 1907/2006, intentionally produced at nanometric scale, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for a minimum proportion of particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm*."

[20] http://www.afssa.fr/Documents/AP2008sa0407.pdf

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"Substance at nano scale contained in a mixture without being linked to it": substance at nano scale intentionally introduced in a mixture from which it is likely to be extracted or released under normal or reasonably foreseeable conditions of use.

EPDLA Conclusion: Polymer dispersions are out of scope of the French Ministerial Order on annual declaration of substances with nanoparticles. According to REACH and the Q&A No. 20-bis of the French decree[21] waterborne polymer dispersions are mixtures. They are consisting out of at least two substances, namely water and polymer.
During the manufacturing process of waterborne polymer dispersions at no point in time nano scaled substances are intentionally added to the mixture.

Thus, neither a nano scaled substance was intentionally added to a mixture nor is the resulting mixture a substance according to REACH and Q&A No. 20-bis of the French decree, nor is the mixture a material/article according to REACH and Q&A No. 20-bis of the French decree out of which a nano scaled substance may be released under reasonable and foreseeable conditions of use: waterborne polymer dispersions are therefore not covered by the French decree so that no declaration/registration is needed.

Denmark – Statutory Order 644 of 13 June 2014
Excerpt of scope:
"§ 2. The reporting requirement to the nano product register includes mixtures and articles that are intended for sale to the general public and which contain nanomaterials, where the nanomaterial itself is released under normal or reasonably foreseeable use of the mixture or article or where the nanomaterial itself is not released but substances in soluble form that are classified as CMRs or environmentally dangerous substances are released from the nanomaterial; …."

EPDLA Conclusion: Polymer dispersions are out of scope of the Danish Statutory Order 644 because no polymeric particles of nano scale are released under reasonably foreseeable use. Besides, the polymer particles are dispersed in water, embedded and stabilized in the liquid matrix. Furthermore, the existence of the waterborne environment is a prerequisite.

Belgium Federal Public Service for Public Health, Food Chain Safety and Environment – Royal decree regarding the placement on the market of substances manufacture at the nanoscale, 27 May 2014 and its modification from 22 December 2017
Excerpt of the definition:
"Substance produced in nanoparticle state: a substance that contains particles being in an unbound state or as an aggregate or as an agglomerate and from which minimum 50 % of the particles have a

[21] Q&A published on 12 March 2013 by the Ministry of Ecology, Sustainable Development, Transport and Housing on articles R 523-12 to R. 523-21 of the French decree no. 2012-232 of 17 February 2012 (https://www.r-nano.fr/)

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quantified size distribution with one or more external dimensions in the range of one to hundred nanometer, …"

EPDLA Conclusion: Polymer dispersions are out of the scope of Belgium Royal Decree. The polymer particles are dispersed in water, embedded and stabilized in the liquid matrix and hence bound in water. Furthermore, the existence of the waterborne environment is a prerequisite.
Moreover during further processing the polymer particles will converge to form a continuous film or matrix.

Notifications to BAG in Switzerland according to Swiss Chemical Ordinance Art. 48-54
Excerpt of the Guidelines for notification, reporting and declaration of new substances: Nanomaterials purposefully containing fibres or tubes with a length of more than 5 µm. must be reported with the notification authority for chemicals (article 48 ChemO) unless they are listed as an exception under article 54 ChemO.

EPDLA Conclusion: Polymer dispersions do not need to be notified to the Swiss authorities unless they are classified as dangerous substances or mixtures, are PBT2 or vPvB3 (article 4 ChemO), are on the candidate list (substances of very high concern), or contain fibres or tubes with a length of more than 5 µm.

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About EPDLA
EPDLA (European Polymer Dispersion and Latex Association), a Cefic Sector Group founded in 1991, is dedicated to promote the safe manufacture, transportation, distribution, handling and use of waterborne polymer dispersions, in compliance with regulatory requirements and industry guidelines. EPDLA members are committed to Responsible Care® principles and have implemented risk management according to the precautionary principles.