

Guideline regarding the Poison Center Notification obligations of Annex VIII CLP for classified water-based polymer dispersions and some options for mixtures not classified as hazardous

Introduction

EPDLA (European Polymer Dispersion and Latex Association, a Cefic Sector Group) is dedicated to promoting 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.

Polymer dispersions are used as raw materials (binders) in many waterborne applications, for example in adhesives, varnishes and coatings, printing inks, nonwovens, paper and paperboard and textile finishing agents. Polymer dispersion technology has been used safely and successfully for more than 50 years and has contributed significantly to a reduction in the release of organic solvents into the environment. The use of polymer dispersions has helped to reduce the use of organic solvents in workplaces leading to improved worker health and similarly has contributed to cleaner air in the home. Common to all dispersions and covered by this statement, is a film forming process during application.

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Summary

Polymer dispersions are mixtures as defined under Article 3(2) of the REACH Regulation, consisting mainly of water and high molecular weight polymer droplets. They are also subject to Regulation 1272/2008 EC (CLP) where applicable.

Article 45 of the CLP regulation 'required the EU Member States to appoint a body for receiving information on the composition of hazardous mixtures to enable the formulation of preventive and curative measures.'¹

After consultation with the stakeholders Commission Regulation (EU) 2017/542 was adopted, adding Annex VIII to the Regulation.

¹ Guidance on harmonised information relating to emergency health response – Annex VIII to CLP, Draft Version 1.0, March 2018



Annex VIII of CLP requires the submission of information about mixtures that are placed on the EU market and classified as *hazardous* based on their *health* or *physical* effects. It means that all mixtures meeting the criteria defined in Part 2 and Part 3 of Annex I of CLP fall under the scope of Article 45 and Annex VIII.

Among the mixtures which fall under the scope of the CLP Regulation, some exemptions apply:

- mixtures classified for environmental hazards *only*;
- mixtures which are subject to supplemental labelling requirements according to Part 2 of Annex II to CLP (i.e. EUH 208) but are not themselves classified for health or physical hazards.

Polymer dispersions fall mainly under the category of non-classified mixtures (with rather few exceptions mainly related to the presence of some additives i.e. biocides, residual monomers etc.) and are therefore, exempted from submission obligations.

For mixtures which are not subject to submission obligations, submission may be done on a voluntary basis. This could be the case for example for mixtures classified for environmental hazards only, or mixtures classified as gases under pressure only (or a combination of the two), or non-classified mixtures (possibly those subject to supplemental labelling information in accordance to Part 2 of Annex II to CLP).

Mixtures for which submission of information is not required can be also used in the formulation of other classified mixtures (mixture in a mixture or MiM) generating potential gaps in the knowledge of mixture composition. When the duty holder does not know the composition of the MiM, it would rely on the Safety Data Sheet (SDS) of that mixture (if available), which does not provide all the relevant information.

The supplier could, following a submission made voluntarily, communicate the compositional information via the Unique Formula Identifier (UFI) that allows the poison centres to identify the product while ensuring the protection of confidential business information. A submission made voluntarily for a mixture to be used in another mixture might allow the emergency responder to retrieve all the necessary information.

Mixture components classified as hazardous based on their health or physical effects are to be included in the submission if they are identified and present in concentrations $\geq 0.1\%$. They are also to be included in the submission if they are identified (even if in concentrations lower than 0,1 %) unless the submitter can demonstrate that those components are irrelevant for the purposes of emergency health response and preventative measures

Mixture components not classified as hazardous based on their health or physical effects are to be included in the submission if they are identified and present in concentrations $\geq 1\%$. For further details please see Part B of Annex VIII.



Deadlines

The compliance date for the submission of the information following the new requirements set by the amended CLP Regulation will apply in a stepwise manner, according to the use type of the mixture i.e. consumer, professional or industrial use.

Importers and downstream users placing mixtures on the market not notified already under national legislation must comply with Annex VIII of the Regulation from the following dates:

- Mixtures for consumer use and mixtures for professional use: from 1 January 2021.
- Mixtures for industrial use: from 1 January 2024.

Before these dates, mixtures continue to be subject to existing national requirements.

Until those dates, there is also no obligation to include the UFI (Unique Formula Identifier) on the label. Hence, the time for including the UFI on the label should coincide with the submission of harmonised information. It is not recommended to place the UFI on the label if that UFI has not been included in a valid notification to the relevant Member State to avoid 'empty' UFI's.

For new mixtures placed on the market after those dates, information needs to be submitted according to Annex VIII. If a company has already submitted information relating to hazardous mixtures to an appointed body in accordance with Article 45(1) before the relevant compliance date (i.e. according to the notification requirements existing at that time in any given Member State), there is no obligation to comply with Annex VIII until 1 January 2025 (transitional period), except in cases where there is a need to provide updated information.

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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 and lattices and 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.

