

28th July 2014

EPDLA fact sheet on the use of biocides in polymer dispersions

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, 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.

EPDLA fact sheet

This fact sheet is considered necessary due to the fact that EPDLA is concerned that because of more stringent upcoming legislation on biocides, an unjust image and positioning of biocides and biocide-containing polymer dispersions could develop creating an undesired situation.

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 dispersions are mixtures as defined in the REACH Regulation, consisting mainly of water and high molecular weight polymer particles. The polymer dispersions 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.

Biocides

Biocides are chemicals used to suppress microorganisms that are harmful to human or animal health, or that cause damage to natural or manufactured materials. These harmful organisms include e.g. moulds (fungi and yeasts), bacteria and algae. Biocides are added to many water based consumer goods such as cosmetics and detergents to inhibit growth of microorganisms and to ensure a minimum shelf life of such products.

Aqueous polymer dispersions need biocides as some bacteria, fungi and yeasts are capable of surviving or multiplying in these substances. These microorganisms are naturally occurring, simple life forms that break down complex structures into simple fragments. They are fundamental and essential life forms which are present everywhere including air, water, and soil. Clearly it is not possible to avoid contact with microorganisms and for this reason it is necessary to protect aqueous products like polymer dispersions and latices by the addition of biocides.

Dispersions contaminated with microorganisms are normally unusable for end users: microbial attack may, for example, lead to an unpleasant smell, discoloration, phase separation or coagulation and thereby have a severe detrimental effect on the technical



properties of a dispersion. Moreover, presence of microorganisms can be harmful to human or animal health.

According to the EU Biocide Regulation (528/2012/EU), aqueous polymer dispersions are treated articles if they contain ("are treated with") biocidal products for in-can preservation. As such the dispersions do not need to be labelled unless the approval of the applied active substances requires so, or a biocidal property for the product is explicitly claimed. The biocides are added only to assure the shelf life of the product during storage and transport to the customer. They are not meant to exert a downstream biocidal effect.

The selection of biocides used in aqueous polymer dispersions is limited as the active substance needs to be approved in EU, needs to be effective and cannot bias the properties of the product or the finished product in which the dispersion is used.

The 2nd ATP of Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP) of substances and mixtures (EU 286/2011)

The 2nd adaptation to technical and scientific progress (ATP) of the Regulation (EC) No. 1272/2008 (GHS/CLP Regulation) addresses the issue of labelling provisions to protect a number of individuals already sensitized to a specific chemical that may elicit a response at a very low concentration. These include skin and respiratory sensitizers.

This 2nd adaptation of CLP has changed the criteria for supplemental labeling of mixtures that contain small amounts of sensitizing substances. The amended criteria for supplemental labeling statement EUH 208 must be applied as of June 1, 2015.

The labeling statement EUH 208 "*Contains [name of sensitizing substance]. May produce an allergic reaction*" is not fundamentally new but has been applicable in Europe since May 31, 1999.

However, the above amendment has tightened the criteria for the application of EUH 208. Whereas until now the limit for sensitizing substances was 1000 ppm, in 2015 the limit for allergens with high sensitizing potential will be reduced to 100 ppm. In the case of allergens with high sensitizing potential which have a substance-specific limit for classification and labeling of less than 1000 ppm, the threshold value for the application of EUH 208 is a tenth of the substance-specific limit. The supplemental labelling concerns mixtures that might eventually cause an allergic reaction of already sensitized persons. Such mixtures containing sensitizing substances need to be labelled depending on general or substance specific concentration limits according to the limits given in the CLP regulation.

The EUH 208 labeling statement is a naming obligation and does not imply that the product is in any way more hazardous as it has been. It is given to inform the small number of individuals that have previously been sensitized to these substances and can have a reaction to these at very low concentrations. The EUH 208 label shall not be confounded with a hazard label and it must not be confused with the classification and labeling of mixtures as "sensitizing". The limit values for classifying and labeling mixtures as sensitizing are higher than those for the application of labeling statement EUH 208.



Sensitizing substances present in aqueous polymer dispersions that would trigger the application of labeling statement EUH 208 are in most cases biocidal active substances that can cause skin sensitization.

As a matter of fact, only a very limited number of biocidal active substances is suitable to preserve polymer dispersions and not every biocide is apt to protect a specific polymer dispersion product - this depends for example on the chemistry involved (e.g. monomer and redox systems). New biocidal active substances sometimes still lack compliance with regulations relevant for dispersions based customer products like e.g. food contact approval (BfR XIV recommendation, FDA regulations and EU 10/2011) or ecolabel criteria.

EPDLA position

Members of EPDLA have for many years invested in R&D to optimize in-can preservation, balancing the risk of microorganism growth in the product and using safe, approved biocides at the lowest possible concentration in a responsible manner. The objective of biocidal treatment is to set the quantity of added biocide only as high as absolutely necessary. The key requirement with regard to biocidal treatment is to set the amount of added biocide at such a level that, if the dispersion is stored correctly, there will still be sufficient preservative protection even towards the end of the product's shelf life.

In this regard, our members have achieved a high level of safety and effectiveness. Their efforts will continue optimization to assure a stable and suitable storage preservation of polymer dispersion products according to the precautionary and Responsible Care® principles. In order to assure sufficient in-can preservation and to assure best possible user and consumer protection, particularly of already sensitized people, EPDLA members are convinced, that the EUH 208 label should not be confounded with a tool to stigmatize biocides but poses a suitable and responsible tool to assure user and consumer information and protection.

- The present position paper has been developed by EPDLA members in good faith, to the best of its knowledge and following the latest scientific evidences.
- 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.