

Proposal for a regulation

Annex II – paragraph 1 – point -1 (new)

Regulation (EC) 1272/2008

Annex II – Part 3 – Section 3.1.1.1

[amendment 94 voted in ENVI](#)

-1 *In Annex II, in Part 3 of Annex II to Regulation (EC) No 1272/2008, point 3.1.1.1. is amended as following:*

"3.1.1.1. Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, or skin corrosion category 1, **or serious eye damage category 1** shall be fitted with child-resistant fastenings."

[EPP plenary amendment 103](#)

-1 *In Annex II, in Part 3 of Annex II to Regulation (EC) No 1272/2008, point 3.1.1.1. is amended as following:*

"3.1.1.1. Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, skin corrosion category 1, **or serious eye damage category 1 with pH ≤ 2 or pH ≥ 11,5** shall be fitted with child-resistant fastenings."

[Renew plenary amendment 107](#)

-1 *In Annex II, in Part 3 of Annex II to Regulation (EC) No 1272/2008, point 3.1.1.1. is amended as following:*

"3.1.1.1. Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, skin corrosion category 1, **or serious eye damage category 1 (which is not fully reversible on the eye)** shall be fitted with child-resistant fastenings."

Extending the requirement for a child-resistant fastening (CRF) to all consumer mixtures classified as serious eye damage Cat. 1 would be disproportionate and will have unintended negative consequences on safety in practice. Consumer research has shown that consumers will fail to reclose packaging, or will transfer products to another container to avoid challenging or time-consuming manipulations. It would also impact negatively on other vulnerable populations, such as the elderly.



- Daily use products such as hand dish wash liquid, laundry detergents and all-purpose surface cleaners are often classified as serious eye damage Cat. 1.
- Studies by Poison Centres and industry have shown a poor correlation between CLP classification and the severity of effects on the eye. Severe eye damage symptoms are typically only observed in accidents with products like drain cleaners, which are also classified as corrosive to the skin (and hence already carry a CRF under existing CLP requirements).
- Serious eye damage Cat. 1 is defined by the OECD and GHS as tissue damage in the eye or serious physical decay of vision following the application of a chemical to the surface of the eye (without any mitigation such as rinsing), and which is not fully reversible within 21 days of application. (CLP Annex I Table 3.3.1)
- In principle this outcome should only arise with the most hazardous chemicals. However due to the practical implementation of the criteria for mixtures as well as pure substances, a much wider range of products can be classified as serious eye damage Cat. 1, despite a very limited number of cases of irreversible damage observed in practice.
- Under CLP criteria it is not possible to make a meaningful differentiation between irreversible and reversible effects on the eye within the hazard category of serious eye damage Cat. 1. Effects that are fully reversed within the observation period of 21 days would normally be classified as eye irritation Cat. 2 (CLP Annex I Table 3.3.2).
- Furthermore, including a qualifier of reversibility in the CRF requirement for eye Cat. 1 would stimulate additional animal testing by formulators in order to fully characterise the effects of their mixtures on actual eye tissue.
- The CLP classification criteria acknowledge that for mixtures containing strong acids or bases, the pH shall be used for classification since pH will be a better indicator of serious eye damage than generic concentration limits (CLP Annex I 3.3.3.3.4.2). pH is a simple laboratory test using indicators or equipment and does not imply any testing on animals.
- Products with extreme pH – i.e. 2 and below or 11,5 and above – are the most likely to cause irreversible effects on the eye. It would therefore be appropriate to require a CRF for any substance or mixture supplied to the general public that is classified as serious eye damage category 1 and has a $\text{pH} \leq 2$ or $\text{pH} \geq 11,5$, in order to impede the access of children to these products.

