

# 18th ATP to the CLP Regulation

TÜV Rheinland LGA Products - Information

July 2022

On May 3rd, 2022, the [Delegated Regulation \(EU\) 2022/692 \(18th ATP\)](#) amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation, Classification, Labelling and Packaging) was published in the Official Journal of the European Union.

With the Adaptation to Technical and Scientific Progress (ATP), new substances are generally included and the classification of existing substances is adjusted.

For all new or updated harmonized classifications a transition period has been granted for compliance allowing suppliers to change the labelling and packaging of substances and mixtures to meet with the new or amended classification and to sell any remaining stock in accordance with the previously applicable regulatory requirements.

The amending Regulation will enter into force on May 23rd, 2022, and will be mandatory for all amendments from December 1st, 2023.

## MAIN CONTENTS OF THE 18TH ATP

In Table 3 of Annex VI, Part 3 of the CLP Regulation, 39 substances have been newly included, 17 existing entries have been amended and one entry has been deleted.

New entries include harmonized classifications for the following substances:

- 4,4'-sulfonyldiphenol; Bisphenol S (CAS No. 80-09-1; Repr. 1B);
- Benzophenone (CAS No. 119-61-9; Carc. 1B);  
Photoinitiator used, among other things, to harden printing inks in UV light. It is possible that the labelling of corresponding mixtures, e.g. printing inks, changes. Furthermore it is used as a stabilizer in cosmetics, waxes and also polymers. Benzophenone is also known degradation product of the UV filter Octocrylene.
- C.I. Disperse Blue 124 (CAS No. 15141-18-1; Skin Sens. 1A);  
Dye stuff in textile dyeing - should not be used in the textile dying process since many years.
- Perfluoroheptanoic acid (CAS No. 375-85-9; Repr. 1B, STOT RE 1);
- 2,4,6-triamino-1,3,5-triazine; melamine (CAS No. 108-78-1; Carc. 2, STOT RE 2)  
Commonly used starting material for synthetic resins (e.g. melamine-urea-formaldehyde resins), additionally Melamine is on the list of "Registry of SVHC intentions". It can be assumed that the substance will be declared as SVHC in 1-2 years.
- Sodium pyrithione (CAS No. 3811-73-2; 15922-78-8, a.o. Skin Sens. 1, STOT RE 1);  
Approved biocide for various product types (PT02, 06, 07, 09, 10 and 13). The labelling of the respective mixtures with this biocide may change
- and others

Among others, the harmonized classifications for substances or substance groups such as:

- Cumene (CAS No. 98-82-8, new Carc. 1B);
- 2-Butoxyethanol (CAS No. 111-76-2; new Skin Irrit. 2);
- 2-(2-methoxyethoxy) ethanol; (CAS No. 111-77-3; new Repr. 1B);  
Both 2-butoxyethanol and 2-(2-methoxyethoxy) ethanol are components of commercially available paints, e.g. spray cans. It can be assumed here that the labelling of the mixtures will change at higher contents of these substances.
- 4,4'- Isopropylidenediphenol; Bisphenol A (CAS No. 80-05-7; new a.o. Aquatic Acute 1);
- 2-ethylhexanoic acid and its salts (CAS No. -; new Repr. 1B);
- Cyfluthrin (ISO) (CAS No. 68359-37-5; new a.o. STOT SE 1);
- beta-cyfluthrin (ISO); (CAS No. 1820573-27-0; new a.o. STOT SE 1);
- and others

Entry deleted:

- 1,5-naphthylene diisocyanate (Index No. 615-007-00-X).

By way of derogation, substances and mixtures may be classified, labelled and packaged in accordance with this Regulation as from the date of its entry into force.

Please note that the 18. ATP changes the classification of some authorized cosmetic ingredients like 2-Butoxyethanol. For those affected substances, it is required to verify and update the safety assessment of the cosmetic product accordingly.

#### INFORMATION ON BORATES (IMPLEMENTATION 17. ATP)

For various borates, the classification-relevant concentration limit is lowered with the 17. ATP because the previous Specific Concentration Limit (SCL) for Repro. 1B is replaced by the stricter Generic Concentration Limit (GCL Generic Concentration Limit) (0.3 %).

In various application areas (including pool chemicals, detergents and cleaners, biocides and soldering aids), mixtures with contents above 0.3 % of these boron compounds are on the market. For these mixtures, the formulation has to be adjusted until December 17th, 2022.

In the case of toys, it should be noted that in the future not only the migratable boron according to EN 71-3, but also the boron content must be critically considered for slimes. If higher concentrations are present, it may be the case that EN 71-3 is fulfilled, but the requirements of the Toy Safety Directive regarding CMR substances are not met.

The German Federal Institute for Risk Assessment (BfR) has recently published a statement on the health risk posed by boron compounds in “wobbling” masses such as play slime and bouncy dough ([BfR statement no. 013/2022](#) of June 16th, 2022).

The BfR concludes that sudden health effects from a single ingestion of a larger quantity of about five grams of “wobbled” mass are very unlikely. Additionally chronic adverse health effects from daily play with wobble are very unlikely in the BfR's view.

For further information, please refer to the BfR statement no. 013/2022.

## CURRENT INITIATIVE FOR THE ADAPTATION OF THE CLP REGULATION

The European Commission has also published on its website ([Have your say](#)) an initiative to adapt the CLP Regulation. The draft legislation is open for comments until July 20th, 2022.

This initiative will include new comments and guidance on boron compounds and 2-ethylhexanoic acid, which will relate the classification of mixtures as toxic for reproduction to the sum of the concentrations in the mixture of the individual substances covered by an entry. The principle of additivity should apply to substances whose hazard is due to the presence or formation of a common molecular unit.

Further information on current legal changes can also be found on our homepage at [www.tuv.com](http://www.tuv.com) or <https://www.tuv.com/regulations-and-standards/en/>.

Further technical information can be obtained from:

### **TÜV Rheinland LGA Products GmbH**

Technical Competence Center Softlines

Dr. Greta Dau

[Greta.Dau@de.tuv.com](mailto:Greta.Dau@de.tuv.com)

Am Grauen Stein 29

51105 Cologne

Germany

**Info box:** For additional information about REACH Services please see <https://www.tuv.com/world/en/reach.html>

Dr. Kathrin Birkmann

[Kathrin.Birkmann@de.tuv.com](mailto:Kathrin.Birkmann@de.tuv.com)

Tillystraße 2

90431 Nuremberg

Germany

Steffen Tuemptner

[Steffen.Tuemptner@de.tuv.com](mailto:Steffen.Tuemptner@de.tuv.com)

Alboinstr. 56

12103 Berlin

Germany

#### Disclaimer

This newsletter contains only information of a general nature without specific reference to particular natural or legal persons, objects or facts. This newsletter is not to be understood as legal advice and does not replace such advice in any case. TÜV Rheinland LGA Products GmbH (TRLPG) cannot guarantee that all formulations correspond exactly to the respective official versions. TRLPG makes every effort to ensure that the information provided is correct and up to date. Nevertheless, errors and ambiguities cannot be completely ruled out. TRLPG therefore accepts no responsibility for the topicality, correctness, completeness or quality of the information provided. For the official text, please refer to Official National or EU Journal.

Liability claims regarding damage caused by the use of any information provided, including any kind of information which is incomplete or incorrect, will therefore be rejected.