

REACH on the Topic of Lead

The EU Commission published Regulation EU 2015/628 in April 2015. It applies to all products placed on the market on or after 1 June 2016 and amends Entry 63 in Annex XVII of the REACH Regulation limiting the use of lead and lead compounds. In addition to the existing regulations for jewellery and articles made of metal, the new text also addresses the lead content of articles which can be placed in the mouth by children.

The chemical element lead numbers among the heavy metals and has impacts on humans and the environment; in humans particularly on haematopoiesis and the nervous system. Lead exposure is especially dangerous in young children as their brain and central nervous system are still developing. At the end of April 2015, the Commission therefore issued a restriction of the content of lead for products or the accessible parts thereof which, during normal or reasonably foreseeable conditions of use, could be placed in the mouth by children.

As a decision criterion as to whether something can be placed in the mouth, the regulation names all components or protruding parts of products smaller than 5 cm in length, width, or height. In the case of footwear, this definition includes components such as laces and Velcro fasteners. The shoes of very young children, for example, can even be smaller than 5 cm in width or height and are thus subject to the regulation as a complete product.



Footwear and articles of daily use would not generally be classified as products that would be placed in the mouth under normal circumstances. However, since small children tend to place all kinds of objects in the mouth, the legislator could argue in the case of infants' or toddlers' shoes that "placing in the mouth" could constitute a foreseeable use.

The limit for the extended ban on lead was set at 0.05 percent by weight. This corresponds to a content of 500 mg of lead per kg of material. If this value is exceeded in an article or in a part thereof, then a migration test is to be performed. If the rate of lead release lies below $0.05 \mu\text{g} \cdot \text{cm}^{-2} \cdot \text{h}^{-1}$ then the material may be used, even if the overall concentration of lead exceeds 500 mg per kg. If the rate of lead release exceeds the limit then the product may not be placed on the market.

A transition period applies for implementation of the regulation. All products first placed on the market prior to 1 June 2016, as well as a number of articles or groups of articles, are exempt from the regulation.

Further information:

Dr. Michael Knauer

Head of Chemical Analysis and Research

Marie-Curie-Str. 19, 66953 Pirmasens

Tel: +49(0)6331 24 90 717

E-Mail: michael.knauer@pfi-germany.de