

EU: New Nickel Release Test Methods Published

A new revision of European Standard EN 1811, and a new test method EN 16128, have been published. EN 1811 is a test method to determine the release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles coming into direct and prolonged skin contact; EN 16128 is a new test method for determination of the release of nickel specific for spectacle frames and sunglasses. The scope of the former EN 1811:1998 + A1:2008 is now divided into: EN 1811:2011 and EN 16128:2011. This standard will be repealed by March 2013.



Background

Nickel is a common metal often combined with other metals to create alloys with increased hardness and resistance to corrosion. However, the presence of nickel in certain products which are intended to come into direct and prolonged skin contact may cause sensitization of humans to nickel and may lead to allergic reactions. Nickel released is regulated under EC 1907/2006 REACH Annex XVII, Item 27 with the following limits. EN 1811:2011 and EN 16128:2011 will be used to verify the conformity of the products to the regulation.

Products	Limit
Any post assemblies which are inserted into pierced ears and other pierced parts of the human body	0.2 $\mu\text{g}/\text{cm}^2/\text{week}$
Articles intended to come into direct and prolonged contact with the skin such as: earrings, necklaces, watch straps, and rivet buttons in garments	0.5 $\mu\text{g}/\text{cm}^2/\text{week}$

Key Changes in Test Methods

New test method EN 16128:2011

- Technically unchanged as compared to the former European Standard EN 1811:1988 + A1:2008
- Limited to spectacle frames and sunglasses in the scope

New revision of test method EN 1811:2011

- Correction factor of 0.1 was deleted from the previous version
- Measurement uncertainty must be taken into account
 - Correlation test uncertainty was found to be 46% which is given in the standard
 - Laboratories may use their own internal measurement uncertainty to evaluate the test result
 - Results within the range of uncertainties are inconclusive
 - Stricter requirement will increase failure rate

Concentration measured ($\mu\text{g}/\text{cm}^2/\text{week}$)	Limit ($\mu\text{g}/\text{cm}^2/\text{week}$)	According to EN 1811: 2011 (using 46% uncertainty for evaluation)
< 0.11	0.2	Pass
0.11 – 0.35		Inconclusive
> 0.35		Fail
< 0.25	0.5	Pass
0.28 – 0.88		Inconclusive
> 0.88		Fail
Concentration measured ($\mu\text{g}/\text{cm}^2/\text{week}$)	Limit ($\mu\text{g}/\text{cm}^2/\text{week}$)	According to EN 1811:1998 + A1:2008
≤ 2 (adjusted value: 0.2)	0.2	Pass
> 2 (adjusted value: 0.2)		Fail
≤ 5 (adjusted value: 0.2)	0.5	Pass
> 5 (adjusted value: 0.2)		Fail

Contact Information

If you have any comments and/or questions regarding these requirements, please contact your customer service representative.

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