



EU Nickel Release - New Official Test Methods

Nickel release from metallic articles with direct and prolonged skin contact sold in the EU will now be determined using the latest test methods EN 1811:2011 and EN 16128:2011. These “new” standards were originally published in 2011 (see Sparkle Vol. 596), but have only just become the official EU nickel release test methods when their references appeared in the European Union’s Official Journal (OJ).

Both standards are now harmonised under Entry 27 of REACH Annex XVII, along with the amended wear and corrosion method, EN 12472:2005+A1:2009 which is applied to coated articles prior to testing per EN 1811 or EN 16128. Until 31 March 2013, EN 1811:1998+A1:2008 may still be used to test articles other than spectacle frames and sunglasses.

Metallic articles with direct and prolonged skin contact include, for example:

- Earrings, other ear and body piercing post assemblies
- Necklaces
- Bracelets and chains, anklets
- Finger rings
- Wrist-watch cases
- Watch straps and tighteners
- Rivet buttons, tighteners, rivets, zippers and metal marks, when used in garments
- Spectacle frames and sunglasses

Release of nickel ions from these articles’ metallic materials in direct and prolonged skin contact can cause sensitisation, nickel allergy and in severe cases even nickel dermatitis.

For EN 1811:2011, the main change is the introduction of measurement uncertainty to the nickel release values, which replaces the analytical correction factor in the previous version. This new measurement uncertainty is based on the results of a further interlaboratory study. In the previous standard, the analytical nickel release value was then multiplied by a correction factor of 0.1, to give a corrected value 10 % of the original value. This was intended to take into account large variations in the nickel release values obtained from an earlier interlaboratory study.

Metallic articles (other than spectacle frames and sunglasses) with direct and prolonged skin contact may have nickel release values which fall within the new measurement uncertainty of the limit. Such uncertainty is inherent to any test measurement, with the true value lying somewhere within a statistical band of uncertainty, calculated from many repeat measurements.

Nickel release values whose band of uncertainty overlaps the required limit will now have to be reported as inconclusive results. A conclusive pass or fail result could only be reported if the nickel release value’s band of uncertainty lies either wholly below or above the required limit. Clearly an inclusive result alone cannot provide adequate evidence of compliance. So it may be prudent to retest, trying to obtain a conclusive result, or even, to err on the side of caution, treat an inconclusive result as if it was a fail.

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The tables below highlight the effects on EN 1811 test results of the shift from the old correction factor to the new measurement uncertainty approach for each of the two limits for nickel release values. Clearly the different treatment of the analytical nickel release values in each version of EN 1811 can lead to opposing or now inconclusive results.

Nickel Release from Post Assemblies for Ear and Body Piercing

Nickel Release Value/ µg/cm ² /week		Limit/ µg/cm ² /week	Compliance Assessment	
Analytical Value	Corrected Value (EN 1811:1998+ A1:2008)		EN 1811:1998+ A1:2008	EN 1811:2011
≤ 0.11	≤ 0.011	0.2	Pass	Pass
> 0.11 and < 0.35	> 0.011 and < 0.035		Pass	Inconclusive
≥ 0.35 and ≤ 2.0	≥ 0.035 and ≤ 0.2		Pass	Fail
> 2.0	> 0.2		Fail	Fail

Nickel Release from Other Articles with Direct, Prolonged Skin Contact (Except for Spectacles and Sunglasses)

Nickel Release Value/ µg/cm ² /week		Limit/ µg/cm ² /week	Compliance Assessment	
Analytical Value	Corrected Value (EN 1811:1998+ A1:2008)		EN 1811:1998+ A1:2008	EN 1811:2011
≤ 0.28	≤ 0.028	0.5	Pass	Pass
> 0.28 and < 0.88	> 0.028 and < 0.088		Pass	Inconclusive
≥ 0.88 and ≤ 5.0	≥ 0.088 and ≤ 0.5		Pass	Fail
> 5.0	> 0.5		Fail	Fail

EN 16128:2011, which covers only spectacle frames and sunglasses, is technically unchanged from the previous standard EN 1811:1998+A1:2008. The 0.1 times (10 %) analytical correction factor, as discussed above for the previous version of EN 1811, is retained and thereby offers a more clear-cut conclusion for the nickel release value. (To fail EN 16128 the analytical nickel release value would have to exceed the limit by more than 10 times, so that it still exceeds the limit after correction.) However, per the note in the OJ reference, a new version of EN 16128 will be developed; but further details are awaited.

Intertek has developed analytical methods to verify the release of nickel from metallic articles. By leveraging our local services and global network, we enable our clients to dedicate their primary energies to their core business activities. We offer comprehensive programs and services which draw on our industry specific knowledge and technical expertise. Please contact your local Intertek laboratory for further details of this and our other services.

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