

# SAFEGUARDS

SGS CONSUMER TESTING SERVICES

HARDGOODS, TOYS & JUVENILE PRODUCTS, SOFTLINES

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## EU HARMONISES TESTING METHOD FOR NICKEL RELEASE UNDER REACH

The European Union recently harmonised EN 1811:2011 for compliance with nickel release under ANNEX XVII of REACH. The effective date is 31 March 2013.

The scope of the existing harmonised method for nickel release, EN 1811:1998+A1:2008, covers commodity products intended to come into direct and prolonged contact with the skin, including spectacle frames and sunglasses.

In March 2011, EN 16128:2011 was published as a reference method specifically for nickel release for components of spectacle frames and sunglasses intended to come into close and prolonged contact with the skin. This method is technically unchanged as compared to EN 1811:1998+A1:2008

In August 2011, we informed you about EN 1811:2011 'the new voluntary standard method for nickel release'<sup>1</sup>. This method has a number of changes to EN 1811:1998+A1:2008, including substances used in the preparation of the artificial sweat solution and the expression of results.

On 22 May 2012, Communication 2012/C 142/05 was published in the Official Journal of the European Union (OJEU)<sup>2</sup>. This Communication harmonises the methods i-ii to be deployed for compliance with nickel release under entry 27 of ANNEX XVII of REACH<sup>3</sup>:

- i. EN 1811:2011 'post assemblies inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with skin'. The effective date is 31 March 2013.
- ii. EN 16128:2011 'parts of spectacle frames and sunglasses intended to come into close and prolonged contact with skin'. The effective date is not specified and can be considered as immediate.

Highlights of the Communication and a comparison on the methods for nickel release, EN 1811:1998 + A1:2008, EN 1811:2011 and EN 16128:2011, are summarised in Table 1.



Throughout our global network of laboratories, we are able to provide a range of services, including analytical testing and consultancy for nickel release in consumer products for the EU and international markets. Please do not hesitate to contact us for further information.

<sup>1</sup> [Safeguard 160/11](#)

<sup>2</sup> [Communication 2012/C 142/05, OJEU, 22 May 2012](#)

<sup>3</sup> [Regulation \(EC\) 552/2009, 26 June 2009, OJEU](#)

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PARAMETER	STANDARD METHOD		
	EN 1811:1998 + A1:2008	EN 1811:2011	EN 16128:2011
SUBSTANCE	Nickel release	Nickel release	Nickel release
SCOPE	Products intended to come into direct and prolonged contact with skin	<ul style="list-style-type: none"> <li>Post assemblies which are inserted into pierced parts of the human body</li> <li>Articles intended to come into direct and prolonged contact with the skin</li> </ul>	Spectacle frames and sunglasses intended to come into close and prolonged contact with skin
SWEAT SOLUTION	<ul style="list-style-type: none"> <li>Sodium chloride</li> <li>DL-lactic acid</li> <li>Urea</li> <li>Ammonium solution</li> </ul>	<ul style="list-style-type: none"> <li>Sodium chloride</li> <li>DL-lactic acid</li> <li>Urea</li> <li>Sodium hydroxide</li> </ul>	<ul style="list-style-type: none"> <li>Sodium chloride</li> <li>DL-lactic acid</li> <li>Urea</li> <li>Ammonium solution</li> </ul>
RESULT INTERPRETATION	Test result x 0.1 (adjusted value)	Based on 46% uncertainty, conformity assessment is based on the following <b>≤ 0.5 µg/cm<sup>2</sup>/week (non-body piercing)</b> Pass ≤ 0.28 µg/cm <sup>2</sup> /week Inconclusive > 0.28 but < 0.88 µg/cm <sup>2</sup> /week Fail ≥ 0.88 µg/cm <sup>2</sup> /week  <b>&lt; 0.2 µg/cm<sup>2</sup>/week (body piercing)</b> Pass < 0.11 µg/cm <sup>2</sup> /week Inconclusive > 0.11 but < 0.35 µg/cm <sup>2</sup> /week Fail ≥ 0.35 µg/cm <sup>2</sup> /week  A result in the inconclusive region indicates that the material can be unsuitable and alternative materials should be used	Test result x 0.1 (adjusted value)
REMARK	---	---	Standard is technically unchanged relative to EN 1811:1998 + A1:2008
REQUIREMENT (REACH, ANNEX XVII)	Body piercing < 0.2 µg/cm <sup>2</sup> /week	Non-body piercing ≤ 0.5 µg/cm <sup>2</sup> /week	≤ 0.5 µg/cm <sup>2</sup> /week
EFFECTIVE DATE FOR HARMONISATION	2008	31 March 2013	22 May 2012

## FOR ENQUIRIES:

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