Standard EN 1811 Amended – Rework of Conformity Assessment Deletes “Inconclusive”- Range

The EU standard EN 1811 defines the test method to determine compliance to the Nickel release requirements of 0.5 µg/cm²/week laid down under REACH regulation EC 1907/2006.

Now Amendment A1 2015 was published. According to this, values up to 0.88 µg/cm²/week should be regarded as “PASS” due to the measurement uncertainty of the method.

Background

Nickel is a well-known contact allergen and is used in several metal alloys. The nickel release is regulated under Annex XVII in the REACH regulation in Europe. According to Entry 27 the rate of nickel released in articles intended to come into direct and prolonged contact with the skin should not be greater than 0.5 µg/cm²/week.

EN 1811 defines the test by which compliance to this requirement is determined. So far, according to the standard, results within the range of uncertainties between 0.28 and 0.88 µg/cm²/week are to be considered as “inconclusive”. In practice this lead to the interpretation that any result above 0.28 µg/cm²/week had to be seen critical as it might stray over the legal limit of 0.5 µg/cm²/week.

The now published amendment still recognizes the uncertainty range but gives a changed interpretation of the necessary conformity assessment. According to the new reasoning given under Point 9.2.2 the limit of 0.5 µg/cm²/week shall be considered exceeded only in case the quantified values are greater or equal to 0.88 µg/cm²/week (or 0.35 µg/cm²/week in case of piercing items with a nickel release limit of 0.2 µg/cm²/week).

The below Table summarizes the impact of the changed interpretation:

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>≤ 0.28</td>
<td></td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>&gt; 0.28 - 0.88</td>
<td>0.5*</td>
<td>Inconclusive</td>
<td>Pass</td>
</tr>
<tr>
<td>≥ 0.88</td>
<td></td>
<td>Fail</td>
<td>Fail</td>
</tr>
</tbody>
</table>

The British version of the amended standard, BS EN 1811:2011 + A1:2015, will become applicable starting on 31.August 2015. By this date, the previous version will be repealed.

Other EU countries will issue their national versions of the standard by January 2016 at the latest.

Further Information:
http://shop.bsigroup.com/ProductDetail/?pid=000000000030316120

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