

UNI EN 1811:2011 standard on nickel release

Andrea Friso, Master Alloy Division

REACH Regulation 1907/2006

(point 27, Annex XVII)

Nickel is one of the substances recognised as being harmful to human health.

Its use has therefore been subject to precise restrictions.

Nickel release

- Nickel in contact with skin can generate allergies, skin rashes e dermatites
- UNI EN 1811 born in 1998 for **European Union (27 UE member states)**

Nickel release

UNI EN 1811 first born in 1998...

Applied throughout all European Union (27 UE member states)

EN1811:2011, a reference standard

«A method for simulating the release of nickel from all items inserted into pierced parts of the ear or other parts of the human body and from objects designed to come into direct and prolonged contact with the skin.»

Relevant points

- Applicable on precious and non-precious metals
- Defines the maximum amount of nickel released after reaction on skin
- **Does not prohibit nickel in alloys!!**

Relevant points

...Why not prohibiting nickel completely??

...In other sectors Ni-based alloys are extremely important!

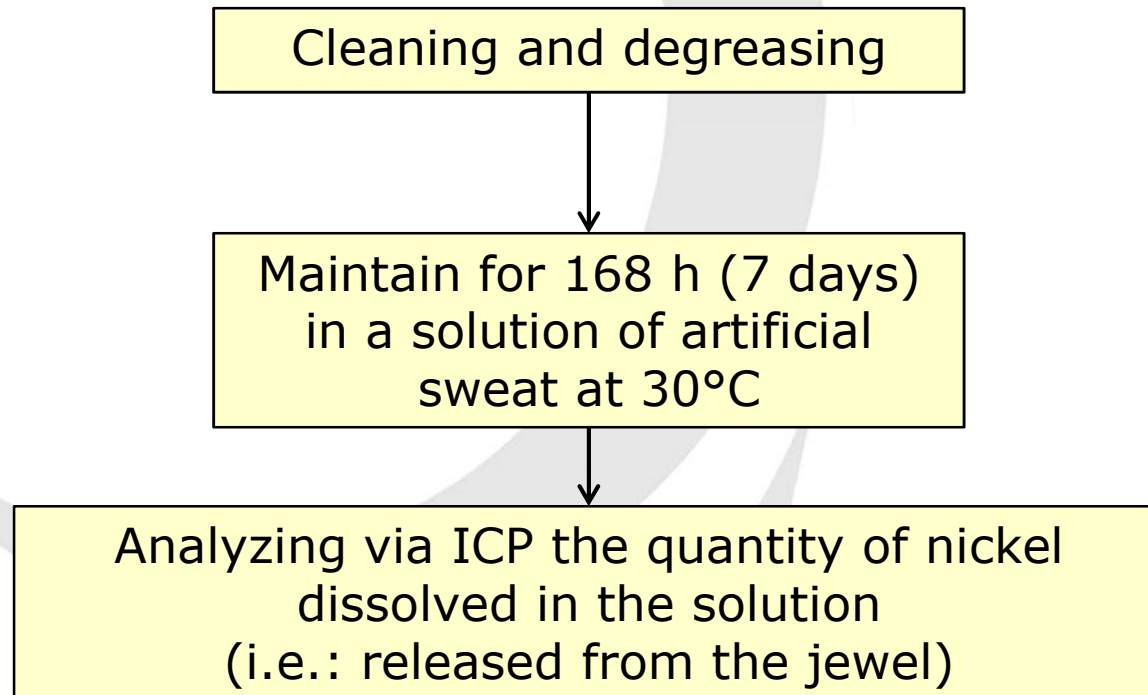
- Steel watches
- Eyewear
- Fashion materials...

EN1811:2011: what has changed

- Enforced in EU on April 1^o, 2013
- Correction factor eliminated: tests are now 10 times stricter!!
- Uncertainty factor of 46% introduced
- Artificial sweat solution modified, slightly more aggressive

Non-coated items

EN1811:2011 artificial sweat corrosion test



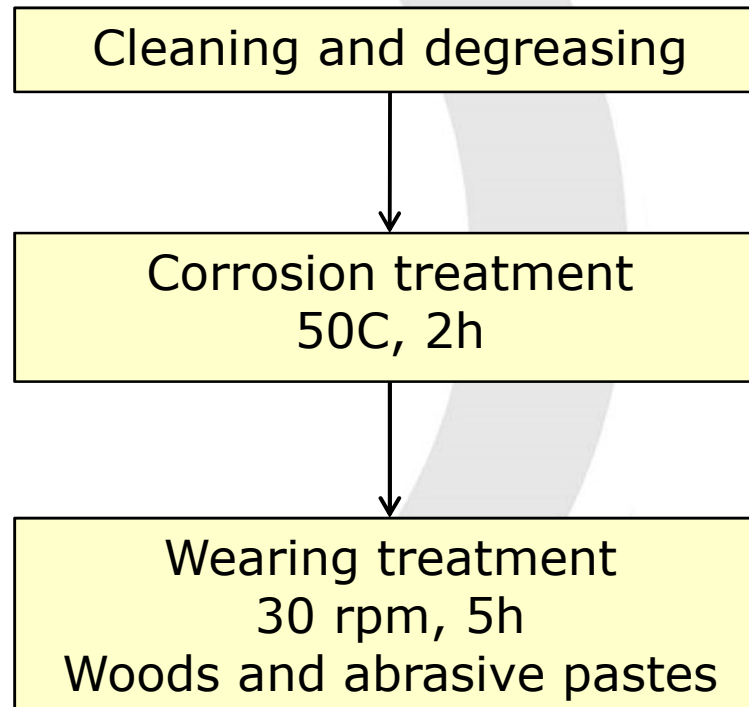
Coated items

If the object is coated:

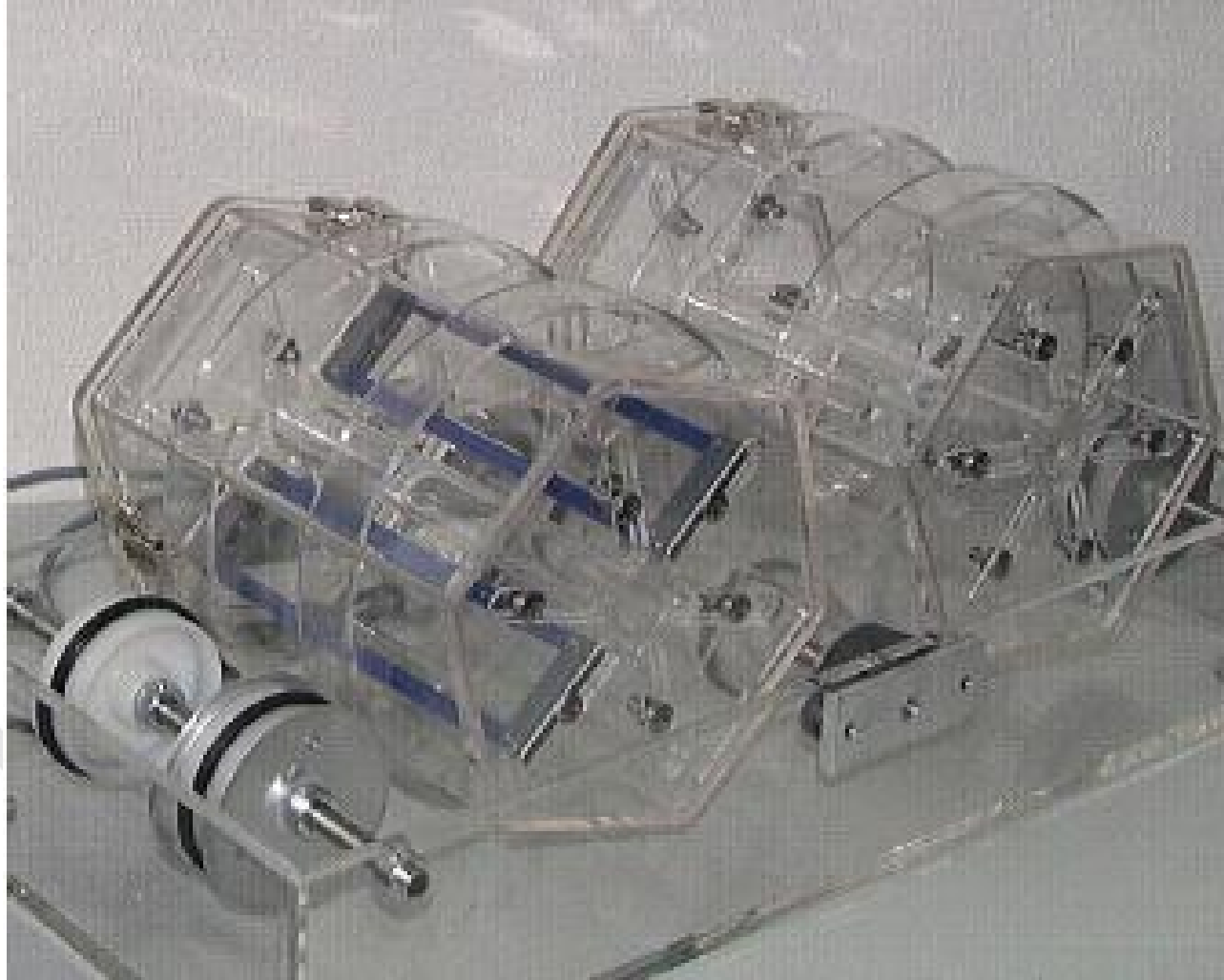
Release value must not exceed $0.5\mu\text{g}/\text{cm}^2/\text{week}$ for a period of 2 years of normal use of the object before it is placed on the market

The method for simulating 2 years of normal wear is defined by the **EN12472:2009** standard

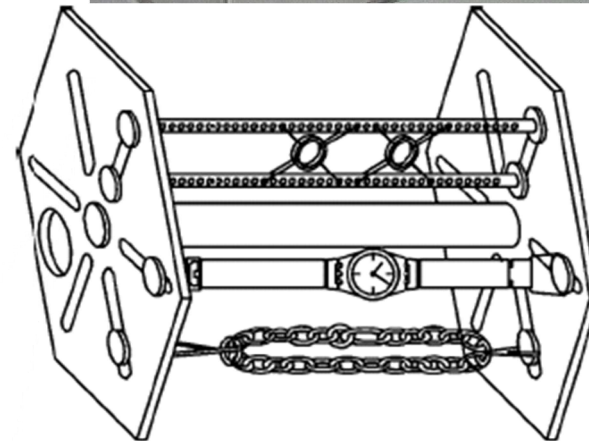
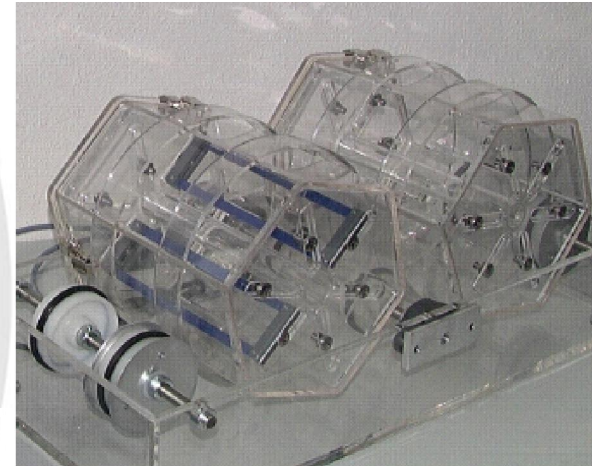
EN12472:2009 before EN1811:2011



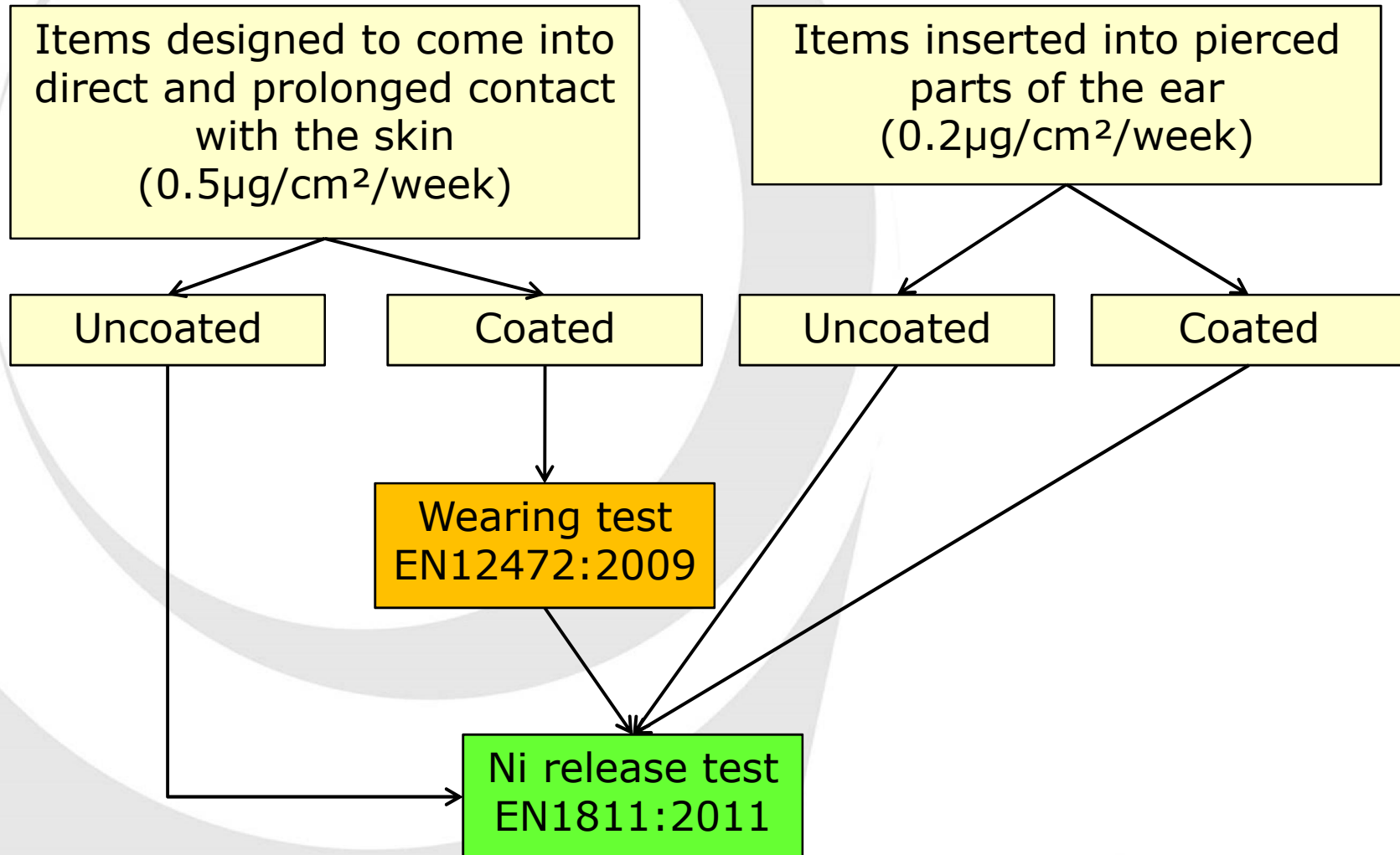
EN12472:2009 – The wearing test



EN12472:2009 – The wearing test machine



REACH point 27 annex XVII Nickel and related compounds



Comparing EN1811:2011 e EN1811:2008

| Ni release value ($\mu\text{g}/\text{cm}^2/\text{week}$) | Limit according to new EN1811:2011 ($\mu\text{g}/\text{cm}^2/\text{week}$) | Result (Uncertainty of 46%) | Effective limit according to old EN1811:2008 ($\mu\text{g}/\text{cm}^2/\text{week}$) |
|---|---|--|--|
| <p><0,11</p> <p>0,11 ÷ 0,35</p> <p>>0,35</p> | <p>0,2 (for objects inserted into pierced parts of the body)</p> | <p>Compliant</p> <p>Non-conclusive</p> <p>Non-compliant</p> | <p>0.05% in weight; 2.0 $\mu\text{g}/\text{cm}^2/\text{week}$ after the 1st april 2005</p> |
| <p><0,28</p> <p>0,28 ÷ 0,88</p> <p>>0,88</p> | <p>0,5</p> | <p>Compliant</p> <p>Non-conclusive</p> <p>Non-compliant</p> | <p>5,0</p> |

Relevant points

- To be on the safe side **do not exceed:**
 - 0.28 $\mu\text{g}/\text{cm}^2/\text{week}$ (non-pierced skin)
 - 0.11 $\mu\text{g}/\text{cm}^2/\text{week}$ (pierced skin)

Weak points

Doesn't take into account individuals that are sensitized to nickel

- After a first allergy rash, less stimulus is needed to trigger it again

Weak points

- Extended statistical uncertainty:
 - Analysis method parameters
 - Surface area measurement
 - Kind of sample

What changes now?

- It is prohibited to produce or to commercialize items that are non-compliant, in any of the 27 UE member States
- **The sole responsible in front of the end customer is the jewelry manufacturing company**

SANCTIONS

Art. 16 – D. Lgs. September 14°, 2009, n. 133
[Extract from italian regulation]

[...] punishment with arrest until three months or fine between 40.000 and 150.000 euros.

Consequences

- Zero Ni release only on Ni-free alloys
- Ni release test becomes mandatory (just like fire assay!)
- Necessary to have a reliable statistic for each production process
- The risk of possible allergic reactions can never be totally excluded!