

EN 1811 is updated for Methods to Analyse Allergens Related to Nickel

On 2023-02-22, the **European Committee for Standardization** (CEN) published the standard **EN 1811:2023** to supersede "EN 1811:2011 + A1:2015". This document specifies a method for simulating the release of **nickel** from all post assemblies which are inserted into pierced ears and other pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin in order to determine whether such articles are in compliance with No. 27 in Annex XVII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)).

Substantial Changes:

Clause(s)	Changes
General	Unit for nickel release "µg·cm ² ·week ⁻¹ " is used, which is equivalent to the unit "µg/cm ² /week" used in the REACH
5.5, 5.6	Added permission for ready-to-use solutions (sodium hydroxide & hydrochloric acid solutions)
5.9	Added notes for the application of wax or lacquer for masking. Samples are dipped into molten wax when using wax; 2 to 3 coats of lacquer might be required when using lacquer
8.2	A note is added for rinsing sample with test solution
8.2	Permission is given for the clarification of filtering release solution, which could be done with syringe filter to avoid damage to the analytical spectrometer or the blocking of instrument's capillary
9.2.2.1	It is now clarified that the nickel release result of each sample has to be compliant with the migration limit when more than one sample of the same article is tested
9.2.2.2	Update the result interpretation for articles with a migration limit of 0.5 µg·cm ² ·week ⁻¹ : the result is compliant when it is ≤ 0.88 µg·cm ² ·week ⁻¹ , instead of <0.88 µg·cm ² ·week ⁻¹ as in the previous version
10	In the new test report requirements, sample area used for calculation and volume test solution could be reported per request
General	Deleted the requirements for quality control material (reference discs)
Annex B.3	Clarified that both test methods should be applied (EN 1811 with and without EN 12472) when uncertainty exists about the presence of nickel in the outer coating
Annex B	Summarized the preparation of samples in table form with added examples. Each individual sub-part shall comply with the requirement of nickel released when it is in direct and prolonged contact with skin. Homogenous sub-part could be obtained by disassembling, cutting or masking
Annex B.4.2.6	There is now a flowchart for sample preparation and test procedure for complete watches

Effective Date:

31 August 2023, which is the "date of publication (dop)" and "date of withdrawal (dow)". This is the latest date by which this EN has to be implemented at national level by publication of an identical national standard or by endorsement, and to withdraw all national standards conflicting with this EN.

Reference:

https://standards.cencenelec.eu/dyn/www/f?p=CEN:110:0:::FSP_PROJECT,FSP_ORG_ID:65837,413439&cs=11CE3B335EC0E7D1F395E7774F8D5B9AD

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