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| logo_ec_17_colors_300dpi | EUROPEAN COMMISSION   |  | | --- | | Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs  Ecosystems I: Chemicals, food and retail  **REACH**  **Bioeconomy, chemicals and cosmetics** Directorate-General for Environment  Circular Economy and Green Growth  **Sustainable Chemicals** | |
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Brussels, 19 April 2021

**Note to the Competent Authorities for REACH and CLP (CARACAL) and observers**

**Concerns: Nickel restriction - Publication of titles and references of standards to be used as the test methods for demonstrating the conformity of articles under entry 27 of Annex XVII to Regulation (EC) No 1907/2006 (REACH)**

**Action Requested: Competent Authorities and observers are invited to take note of the document.**

The restriction on nickel laid down in entry 27 of Annex XVII REACH provides for the standards adopted by the European Committee for Standardisation (CEN) to be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2 of the restriction.

The references of those CEN standards were traditionally published in the C series of the *Official Journal of the European Union* (OJEU) by means of a Commission Communication. In the case of the nickel restriction, the latest publication took place in 2017 (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=uriserv:OJ.C_.2017.011.01.0013.01.ENG>). Information on this Communication was also made available on the Commission webpage on “Harmonised Standards” (<https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en>).

CEN informed the Commission that one of those standards, EN 12472, was updated in 2020. An update of the 2017 list of references is therefore necessary.

The Commission services responsible for REACH, however, will not update this list through a Commission Communication in the OJEU, as done in the past. Instead, the document in annex will be published on the Commission webpage dealing with REACH restrictions (<https://ec.europa.eu/growth/sectors/chemicals/reach/restrictions_en>), updating and replacing the information currently available there. A corresponding link will be made available also on the Commission webpage on “Harmonised Standards”.

This pragmatic approach intends to simplify the current and future updating of the list of references for entry 27. It is also preferred for the following legal reasons:

Although the standards which are to be used for demonstrating conformity with the restriction on nickel were originally developed by CEN on the basis of a standardisation request from the Commission, REACH does not provide for them to be harmonised standards in accordance with Regulation 1025/2012 on European Standardisation, nor for their references to be published in the OJEU. Consequently, their references cannot be published in the same manner as for harmonised standards[[1]](#footnote-1).

**Annex**

**Titles and references of standards to be used as the test methods for demonstrating the conformity of articles under entry 27 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**

**Nickel**

(1) This list replaces the previous list of standards used for the implementation of entry 27 and published in the *Official Journal of the European Union* C 11 of 13.1.2017.

(2)As of April 2021, the titles and references of standards to be used as the test methods for demonstrating the conformity of articles under entry 27 of Annex XVII to REACH will be published on the Commission website only and no publication in the *Official Journal of the European Union* is foreseen anymore*.*

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| European standardisation organisation | Reference and title of the standard | Reference of superseded standard |
| CEN | EN 1811:2011+A1:2015  Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin | EN 1811:2011 |
| CEN | EN 12472:2020  Method for the simulation of accelerated wear and corrosion for the detection of nickel release from coated items | EN 12472:2005+A1:2009 |
| CEN | EN 16128:2015  Ophthalmic optics – Reference method for the testing of spectacle frames and sunglasses for nickel release | EN 16128:2011 |
| Any information concerning the availability of the standards can be obtained either from the European standardisation organisations or from the national standardisation bodies the list of which is published in the *Official Journal of the European Union* in accordance with Article 27 of Regulation (EU) No 1025/2012.  More information about harmonised standards and other European standards is available also at https://ec.europa.eu/growth/single-market/european-standards\_en | | |

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| Language  (other than English) | Title of  EN 1811:2011+A1:2015 | Title of  EN 12472:2020 | Title of  EN 16128:2015 |
| BG | Сравнителен метод за изпитване отделянето на никел, съдържащ се в изделия, поставени в продупчени части от човешкото тяло и продукти, предназначени за директен и продължителен контакт с кожата | Метод за симулиране на ускорено изтриване и корозия за откриване отделянето на никел от продукти с покритие | Офталмологична оптика. Сравнителен метод за изпитване на рамки за очила и слънчеви очила за отделяне на никел |
| CZ | Stanovení niklu uvolněného z výrobků vloených do propíchnutých částí lidského těla a předměty přicházejících do přímého a dlouhodobého styku s pokokou | Metoda simulace zrychleného opotřebení a koroze pro detekci uvolněného niklu z předmětů potaených ochranným povlakem | Oční optika - Referenční metody zkouení na uvolňování niklu z částí brýlových obrub a slunečních brýlí |
| DA | Referenceprøvningsmetode til bestemmelse af nikkelafgivelse fra alle typer ørestikker og piercingstave til indsætning i piercede dele af menneskekroppen og fra artikler beregnet til direkte og længerevarende kontakt med huden | Metode til simulering af fremskyndet slid og korrosion til bestemmelse af nikkelafgivelse fra overfladebehandlede emner | Øjenoptik - Referencemetode for prøvning af nikkelafgivelse fra brillestel og solbriller |
| DE | Referenzprüfverfahren zur Bestimmung der Nickellässigkeit von sämtlichen Stäben, die in durchstochene Körperteile eingeführt werden und Erzeugnissen, die unmittelbar und länger mit der Haut in Berührung kommen | Simulierte Abrieb- und Korrosionsprüfung zum beschleunigten Nachweis der Nickelabgabe von mit Auflagen versehenen Gegenständen | Augenoptik - Referenzverfahren für die Bestimmung der Nickellässigkeit von Brillenfassungen und Sonnenbrillen |
| EL | Μέθοδος δοκιμής αναφοράς για την απελευθέρωση του νικελίου από όλα τα ενθέματα που εισέρχονται σε διατρυπημένα μέρη του ανθρώπινου σώματος και αντικείμενα που προορίζονται να έρθουν σε άμεση και παρατεταμένη επαφή με το δέρμα | Μέθοδος προσομοίωσης της επιταχυνόμενης φθοράς λόγω χρήσης και διάβρωσης για την ανίχνευση της απελευθέρωσης νικελίου από επικαλυμμένα αντικείμενα | Οφθαλμική οπτική - Μέθοδος αναφοράς για τη δοκιμή απελευθέρωσης νικελίου από σκελετούς ομματοϋαλίων και από γυαλιά ηλίου |

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| ES | Método de ensayo de referencia para la determinación de la liberación de níquel en objetos dotados de pasador que se insertan en partes perforadas del cuerpo humano y en productos destinados a entrar en contacto directo y prolongado con la piel | Método de simulación del desgaste y la corrosión para la detección de la liberación de níquel en artículos recubiertos | Óptica oftálmica. Método de ensayo de referencia para la determinación de la liberación de níquel de las monturas de gafas y de las gafas de sol |
| ET | Põhimeetod nikli eraldumise määramiseks needikomplektides, mis läbivad augustatud kehaosi ja toodetes, mida kasutatakse nahaga vahetus pikaajalises kontaktis | Meetod kiirendatud kulumise ja korrosiooni simuleerimiseks nikli eraldumise avastamiseks nikeldatud esemetelt | Oftalmiline optika. Tugimeetod nikli eraldumise määramiseks prilliraamidelt ja päikeseprillidelt |
| FI | Referenssitestimenetelmä liukenevan nikkelin havaitsemiseksi lävistyksissä käytettävistä tuotteista ja tuotteista, jotka on tarkoitettu suoraan ja pitkäaikaiseen kosketukseen ihon kanssa | Kulumista ja syöpymistä simuloiva menetelmä päällystetyistä esineistä liukenevan nikkelin havaitsemiseksi | Silmälääketieteellinen optiikka. Vertailutestimenetelmä nikkelipäästöjen havaitsemiseksi silmä- ja aurinkolasikehyksistä |
| FR | Méthode d'essai de référence relative à la libération du nickel par les assemblages de tiges qui sont introduites dans les parties percées du corps humain et les produits destinés à entrer en contact direct et prolongé avec la peau | Méthode de simulation de l'usure et de la corrosion accélérées pour la détermination de la teneur en nickel libéré par les objets revêtus | Optique ophtalmique - Méthode d'essai de référence relative à la libération du nickel par les montures de lunettes et les lunettes de soleil |
| GA | Modh tástála tagartha le haghaidh scaoileadh nicile as gach iarchóimeáil a chuirtear isteach i gcodanna pollta de cholainn agus ailt an duine atá ceaptha le teacht i dteagmháil go díreach agus ar bonn fadaithe leis an gcraiceann | Modh chun caitheamh agus creimeadh luathaithe a ionsamhlú chun scaoileadh nicil ó earraí brataithe a bhrath | Optaic oftalmach - Modh tagartha chun frámaí spéaclaí agus spéaclaí gréine a thástáil ó thaobh scaoileadh nicil |
| HR | Referentna metoda ispitivanja izlučivanja nikla iz svih dijelova koji se umeću u probušene dijelove ljudskoga tijela i predmeta koji su u izravnom i produženome kontaktu s ljudskom kožom | Metoda za simulaciju ubrzanog trošenja i korozije za određivanje otpuštanja nikla iz prevučenih predmeta | Oftalmološka optika -- Referentna metoda za ispitivanje oslobađanja nikla iz dioptrijskih okvira i sunčanih naočala |

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| HU | Testékszerek és az emberi bőrrel közvetlenül, hosszú ideig érintkező termékek nikkelkibocsátásának referenciavizsgálati módszere | A kopást és a korróziót szimuláló eljárás a bevonatos darabok nikkelkibocsátásának kimutatására | Látszerészet. Szemüvegkeretek és napszemüvegek nikkelkibocsátás tesztelésének referencia módszere |
| IT | Metodo di prova di riferimento per il rilascio di nichel da tutti gli assemblati che vengono inseriti in parti perforate del corpo umano e da articoli destinati a venire in contatto diretto e prolungato con la pelle | Metodo per la simulazione dell'usura accelerata e della corrosione per la determinazione del rilascio di nichel da articoli ricoperti | Ottica oftalmica - Metodo di prova di riferimento relativo al rilascio di nichel da montature per occhiali e occhiali da sole |
| LT | Pamatinis tyrimo metodas nustatyti nikelį, išsiskyrusį iš strypelių sąrankų, įdėtų į persmeigtas žmogaus kūno dalis, ir iš gaminių, tiesiogiai ir ilgą laiką liečiančių odą | Pagreitinto dilimo ir korozijos modeliavimo metodas nikelio išsiskyrimui iš dengtų gaminių aptikti | Oftalmologinė optika. Pamatinis metodas nikelio išsiskyrimui iš akinių rėmelių ir saulės akinių tirti |
| LV | Etalontestēšana niķeļa izdalīšanās noteikšanai elementiem, kas ievietoti caurdurtajās cilvēka ķermeņa daļās un izstrādājumiem, kas paredzēti tiešai un ilgstošai saskarei ar cilvēka ādu | Paātrināta nodiluma un korozijas simulācijas metode niķeļa izdalīšanās noteikšanai no pārklājumiem | Oftalmijas optika. Briļļu un saulesbriļļu rāmju testēšanas references metode niķeļa izdalīšanās noteikšanai |
| MT | Metodu ta' referenza ta' ttestjar għat-tisfija ta' nikil minn tagħmir magħmul minn diversi partijiet li jiddaħħal f'partijiet imtaqqbin tal-ġisem uman u artikoli maħsubin biex jiġu f'kuntatt dirett u fit-tul mal-ġilda | Metodu għas-simulazzjoni ta' kedd u korrożjoni biex wieħed jinduna bit-tisfija ta' nikil minn oġġetti niksija | Ottika oftalmika-Metodu ta' referenza ta' ttestjar għat-tisfija ta' nikil minn dawk il-partijiet ta' frejms ta' nuċċalijiet u nuċċalijiet tax-xemx maħsubin biex ikunu f'kuntatt mill-qrib u fit-tul mal-ġilda |
| NL | Referentie-beproevingsmethode voor de afgifte van nikkel van producten die bedoeld zijn om in direct en langdurig contact te komen met de huid | Methode voor de simulatie van slijtage en corrosie voor het aantonen van de afgifte van nikkel uit voorwerpen die van een deklaag zijn voorzien | Referentie-beproevingsmethode voor de afgifte van nikkel van die delen van brilmonturen en zonnebrillen die bedoeld zijn om in direct en langdurig contact te komen met de huid |

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| PL | Jubilerstwo -- Zalecana metoda badania uwalniania się niklu z części wyrobów umieszczanych w przekłuwanych miejscach ludzkiego ciała oraz produktów przeznaczonych do bezpośredniego i długotrwałego kontaktu ze skórą | Metoda symulacji przyspieszonego ścierania i korozji stosowana do wykrywania uwalniania się niklu z wyrobów z powłoką | Optyka oftalmiczna -- Metoda odniesienia badania uwalniania niklu z oprawek okularów i okularów przeciwsłonecznych |
| PT | Método de ensaio de referência para a libertação de níquel a partir de peças que são colocadas em partes perfuradas do corpo humano e a partir de artigos destinados ao contacto directo e prolongado com a pele | Método para a simulação de desgaste e corrosão para a deteção de libertação de níquel de artigos revestidos | Óticas oftálmicas - Métodos de ensaio de referência relativos à libertação de níquel pelas armações de óculos e de óculos de sol |
| RO | Metodă de încercare de referinţă pentru eliberarea nichelului din ansamblurile de tije care sunt introduse în părţile străpunse ale corpului uman şi produsele destinate să vină în contact direct şi prelungit cu pielea | Metodă pentru simularea uzurii şi a coroziunii accelerate pentru determinarea nichelului eliberat din obiectele acoperite | Optică oftalmică. Metodă de încercare de referinţă pentru eliberarea nichelului din părţile de rame de ochelari sau ochelari de soare |
| SK | Referenčná skúšobná metóda na stanovenie uvoľňovania niklu z predmetov vkladaných do prepichnutých častí tela a z výrobkov prichádzajúcich do priameho a dlhotrvajúceho styku s pokožkou | Metóda na simulovanie opotrebovania a korózie na dôkaz uvoľňovania niklu z povrstvených predmetov | Očná optika. Referenčná skúšobná metóda na stanovenie uvoľňovania niklu z okuliarových rámov a slnečných okuliarov |
| SL | Primerjalna preskusna metoda za sproščanje niklja iz izdelkov, vstavljenih v prebodene dele človeškega telesa, in izdelkov, ki so v neposrednem in daljšem stiku s kožo | Metoda za simulacijo pospešene obrabe in korozije za zaznavanje sproščanja niklja iz prevlečenih predmetov | Očesna optika - Referenčna preskusna metoda za ugotavljanje sproščanja niklja iz okvirjev očal in sončnih očal |
| SV | Referensprovningsmetod för kontroll av frisättning av nickel från alla inlägg som efter håltagning placeras i delar av människokroppen och i artiklar avsedda att komma i direkt och långvarig kontakt med huden | Metod som simulerar nötning och korrosion inför analys av frisättning av nickel från ytbelagda produkter | Ögonoptik - Referensmetod för provning av glasögonbågar och solglasögon med avseende på frisättning av nickel |

1. Article 10(6) of Regulation (EU) No 1025/2012 on European Standardisation requires the Commission to publish references to harmonised standards in the *Official Journal of the European Union* or by other means as laid down in the harmonisation legislation concerned. Note that, following the judgments in Cases C-613/14 (James Elliott) and T-474/15 (Global Gardens), since 1 December 2018, references to harmonised standards are adopted and published by means of Commission Implementing Decisions. Commission Communications as previously used are not sufficient and are therefore no longer being used. For an illustrative example, see Commission Implementing Decision (EU) 2019/1728 on harmonised standards for toys (<https://eur-lex.europa.eu/eli/dec_impl/2019/1728/oj>). [↑](#footnote-ref-1)