

Nickel and cobalt release from metal alloys of tools – a current analysis in Germany

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Summary

Background. The former 'EU Nickel Directive' and, since 2009, the REACH Regulation (item 27 of Annex XVII) do not include all metallic objects. The nickel content of tools is not regulated by the REACH Regulation, even if they may come into prolonged contact with the skin. Tools might be possible sources of nickel and cobalt sensitization, and may contribute to elicitation and maintenance of hand eczema.

Objectives. To perform a current analysis of the frequency of nickel or cobalt release from new handheld tools purchased in Germany.

Methods. Six hundred unused handheld tools from the German market were investigated with the dimethylglyoxime test for nickel release and with disodium-1-nitroso-2-naphthol-3,6-disulfonate solution for cobalt release.

Results. Nickel release was detected in 195 of 600 (32.5%) items, and cobalt in only six (1%) of them. Positive nickel results were nearly twice as frequent in tools 'made in Germany' than in tools without a mark of origin. Tools made in other European countries did not release nickel. Cobalt release was only found in pliers and a saw. A correlation was found between price level and nickel release. Among toolkits, 34.2% were inhomogeneous concerning nickel release.

Conclusion. The German market currently provides a large number of handheld tools that release nickel, especially tools 'made in Germany'. For consumer protection, it seems appropriate to include handheld tools in the REACH Regulation on nickel.

Key words: cobalt; EU Nickel Directive; Germany; handheld tools; nickel; REACH Regulation; release.

The use of tools and their production has been of central importance to the development of humankind. In the modern manufacture of tools, nickel and cobalt are being

used because of their hardening properties and ability to inhibit corrosion, to improve quality. However, nickel and cobalt are frequent contact allergens, as shown by 15.3% and 5.8%, respectively, of the patch tested individuals from the German Contact Dermatitis Research Group/Information Network of Departments of Dermatology (IVDK) (1).

As early as 1990 in Denmark and 1991 in Sweden, a law on nickel restriction was passed: In Denmark, objects intended to come into prolonged contact with the skin were restricted to release of $<0.5 \mu\text{g nickel}/\text{cm}^2/\text{week}$ (2), and in Sweden ear piercing with nickel-containing piercers or studs was banned if the article contained

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>0.05% nickel (3). Shortly thereafter, in 1994, the EU Nickel Directive was introduced (4). Timely incorporation of the directive into national law was successful in several European countries (e.g. Scandinavian countries). The directive came fully into force in the entire EU in 2001 (5, 6), and has been subsumed into the REACH Regulation (item 27 of Annex XVII) since 1 June 2009. It regulates the maximum allowed amount of nickel release from consumer products (4, 7): objects intended to come into direct and prolonged contact with the skin should not release >0.5 µg nickel/cm²/week. The former directive and the current REACH Regulation list examples of such items, including earrings, necklaces, bracelets and chains, anklets, finger rings, wristwatch cases, watch straps and tighteners, rivet buttons, rivets, zips, and metal marks, when these are used in garments. From 2005 on, nickel release from all items inserted into pierced parts of the body (not only during epithelialization after piercing) was limited to <0.2 µg/cm²/week (8). From 2009 on, mobile phones were included in the directive (5, 9). According to the current definition, which was published by the European Chemicals Agency (ECHA) in April 2014 (<http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/restrictions>), 'Prolonged contact with the skin is defined as contact with the skin to articles containing nickel of potentially more than (i) 10 min on three or more occasions within 2 weeks, or (ii) 30 min on one or more occasions within 2 weeks.'

As a consequence of the implementation of the EU Nickel Directive, a slight downward trend in the prevalence of nickel allergy and allergic contact dermatitis in young female patients, from 36.7% in 1992 to 25.8% in 2001, was observed in patch tested clinic patients from the IVDK (Germany, Austria, and Switzerland) (10). From 2005 to 2012, a significant decrease in nickel allergy in the groups of younger women (1–17, 18–30 and 31–44 years) and a significant increase in the older age group (45–60 years) was found (10). The increase in this age group of patch tested clinic patients was explained by a cohort effect [individuals had probably been exposed to 'unregulated' nickel when they were younger, before the first directive of 1994 (11, 12)].

However, the median prevalence of nickel allergy in the general population of North America and western Europe is still high, being currently ~8.6% (13).

Many items in daily use, such as keys, coins, toys, and tools, are not included in the REACH Regulation on nickel (7), and continue to contain and release nickel (14–16). The aim of this study was to perform a current analysis of nickel and cobalt release from handheld tools and small hardware items purchased in Germany. This is particularly important for assessing the presence of nickel

and cobalt in the professional environment as a source of exposure for sensitization and elicitation of contact eczema of the hands.

Materials and Methods

Tools and hardware

From January to October 2013, 600 new, unused handheld tools and small hardware parts (nails, screws, and nuts) from 46 different manufacturers were purchased at specialized hardware stores, home improvement stores, discount stores, or internet stores: wrench keys (n = 156), lathe tools (n = 121), pliers (n = 64), chisels (n = 41), nuts (n = 36), files (n = 32), miscellaneous (n = 31), hammers (n = 30), nails (n = 26), screws (n = 22), spatulas (n = 21), and saws (n = 20) (Table 1).

To evaluate a possible relationship between the price of tools and their nickel release, for the different types of tools [lathe tools, files, chisels, hammers, saws, spatulas, wrenches, pliers, and other miscellaneous tools (cranks, clamps, grips, brackets, scissors, and screwdriver electricity testers)] (n = 516), the individual price range was determined and divided into three terciles (low, medium, and high). Possible differences between the three terciles were calculated with χ^2 square tests. A *p*-value of <0.05 was regarded as significant (Table 2).

Detection of nickel and cobalt release

For detection of nickel and cobalt release, 'reveal and conceal' commercial test kits were purchased from

Table 1. Nickel and cobalt release from handheld tools and hardware by function

Tool	No. tested	No. DMG test-positive	% DMG test-positive	No. cobalt spot test-positive	% cobalt spot test-positive
Chisels	41	13	31.7	0	0
Files	32	17	53.1	0	0
Hammers	30	6	20	0	0
Lathe tools	121	33	27.3	0	0
Nails	26	2	7.7	0	0
Nuts	36	3	8.3	0	0
Other	31	21	67.7	0	0
Pliers	64	34	53.1	5	7.8
Saws	20	8	40	1	5
Screws	22	2	9	0	0
Spatulas	21	6	28.6	0	0
Wrenches	156	50	32	0	0
Totals	600	195	32.5	6	1

The group 'other' includes the following: cranks, clamps, grips, brackets, scissors, and screwdriver electricity testers. The tools were tested with the dimethylglyoxime (DMG) test for nickel release and the cobalt spot test for cobalt release.

Table 2. The price ranges of the calculated terciles of individual tools (tercile 1, low price; tercile 2, intermediate price; tercile 3, high price)

Tool type	Minimum	Maximum	Tercile 1	Tercile 2	Tercile 3	DMG-positive, n (%)	p-value
Chisels	€4.25	€45.90	€4.25–18.13	€18.14–32.01	€32.02–45.90	13/41 (31.7)	0.7300
Files	€3.39	€9.99	€3.39–5.59	€6.60–7.79	€7.80–9.99	17/32 (53.1)	0.0682
Hammers	€2.99	€30.99	€2.99–12.32	€12.33–21.65	€21.66–30.99	6/30 (20)	0.0154
Lathe tools	NA	NA	*	**	***	33/121 (27.3)	0.0003
Other	€6.65	€26.95	€6.65–13.40	€13.41–20.15	€20.16–26.90	21/31 (67.7)	0.8747
Pliers	€1.99	€26.95	€1.99–10.31	€10.32–18.63	€18.64–26.95	34/64 (53.1)	0.2858
Saws	€3.99	€21.50	€3.99–9.82	€9.83–15.66	€15.67–21.50	8/20 (40)	0.1753
Spatulas	€1.90	€8.85	€1.90–4.22	€4.23–6.53	€6.54–8.85	6/21 (28.6)	0.0544
Wrenches	€1.99	€8.50	€1.99–4.16	€4.17–6.33	€6.34–8.50	50/156 (32.1)	0.0017

DMG, dimethylglyoxime; NA, not applicable.

A highly significant correlation between price and nickel release was found for lathe tools ($p = 0.0003$), wrenches ($p = 0.0017$) and hammers ($p = 0.0154$), whereas the correlation for spatulas ($p = 0.0544$) and all other tools ($p = 0.0682$ to $p = 0.8747$) did not reach the level of significance.

*–***All examined lathe tools were from tool sets or cases. Therefore, a price range for the individual lathe tools is not applicable. The lathe tools were grouped on the basis of the price segment of the tool set/case that they were from. For tool sets, these price spans were as follows: tercile 1, €2.79–20.52; tercile 2, €20.53–38.22; and tercile 3, €38.23–56. For tool cases, these price spans were as follows: tercile 1, €34.99–84.40; tercile 2, €84.41–133.81; and tercile 3, €133.82–183.23.

According to this, *67 of 121 lathe tools belonged to tercile 1, **8 of 121 lathe tools belonged to tercile 2, and ***46 of 121 lathe tools belonged to tercile 3.

SmartPractice™ (Phoenix, AZ, USA): Article no. AL 8003 (nickel), using dimethylglyoxime (DMG) for nickel detection, and AL 8004 (cobalt), using disodium-1-nitroso-2-naphthol-3,6-disulfonate for cobalt detection.

Prior to the release test, each tool was cleaned with a cotton cloth soaked in isopropyl alcohol. After the tool had been dried, the nickel detection test was performed on the surface. A new applicator was used for each tool and each test site. The surface was rubbed for at least 60 seconds, and for longer in doubtful cases. A detectable colour change to pink was assessed as a positive reaction. In each case, the qualitative nickel/cobalt detection test was conducted on both the functional area and the grip area. Subsequently, the cobalt testing was performed at a different site on the tool. The nickel and cobalt tests were reproducible. A random sample of 50 tools was tested twice, with a time lag of at least 1 week. We found reproducibility of the previous test results in 100% of the retests. All investigations were performed by the same person (A. Kickinger).

Photographic documentation

Photographs were taken of the test results for all investigated tools and parts. A Canon Coolpix S500 was used under daylight conditions, without a flash. All results were transferred to an Excel™ spreadsheet (Microsoft Office™ 15, Professional Plus, 2012).

Statistics

Data entry was performed with Microsoft Excel™, and statistical analyses were performed with SAS™ 9.1 WIN

(SAS Institute, Cary, NC, USA). The empirical distribution of categorical data was reported with absolute and relative frequencies. Possible differences between groups were calculated with χ^2 tests. A p -value of <0.05 was regarded as significant.

Results

Nickel/cobalt release from handheld tools

One hundred and ninety-five of 600 investigated handheld tools and small parts (32.5%) showed positive nickel release and $n = 6$ (1%) positive cobalt release (Fig. 1a). Nickel release from all parts (grip and functional part) was found in 10.8% of tools ($n = 65$), nickel release exclusively from the grip part was found in 12% ($n = 72$), and nickel release exclusively from the functional part was found in 9.7% ($n = 58$) (Fig. 1b). Pliers and files most frequently showed nickel release (Fig. 3c). Pliers and saws were the only tools that showed cobalt release from their functional areas (Table 1; Fig. 3d).

Nickel/cobalt release from handheld tools by source of supply

Of 257 parts purchased from internet shops, 75 parts (29.1%) showed nickel release; of 166 parts purchased from home improvement stores, 69 parts (41.5%) showed nickel release; of 51 parts purchased from discount stores, 16 parts (31.3%) showed nickel release; and of 126 parts purchased from specialized retailers, 35 parts (27.7%) showed nickel release.

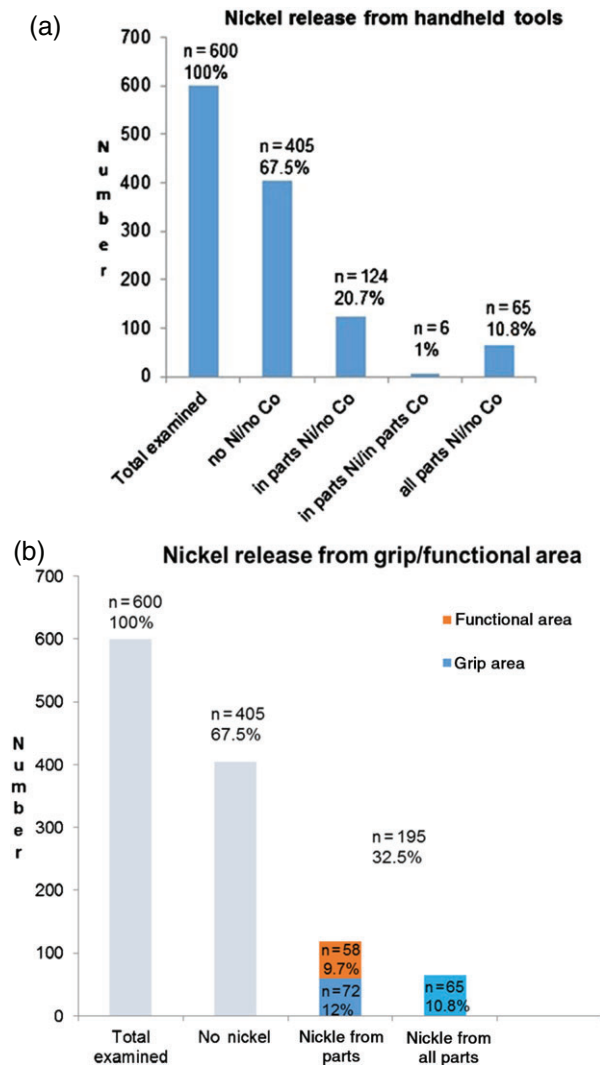


Fig. 1. (a) Nickel and/or cobalt release from 600 examined handheld tools and small hardware parts. Numbers and percentages of tools without nickel/cobalt release, with nickel/cobalt release from parts (either from the functional or the grip area of the tool) or from all parts (the functional and the grip area) are shown. The following combinations of nickel/cobalt release were not found in any of the tools: no nickel/cobalt from parts; no nickel/cobalt from all parts, nickel from parts/cobalt from all parts; nickel from all parts/cobalt from parts; and nickel from parts/cobalt from all parts. (b) Of the examined tools, 32.5% ($n = 195$) showed nickel release (dimethylglyoxime test-positive): 10.8% ($n = 65$) showed nickel release from all parts (grip and functional parts), and 21.7% ($n = 130$) showed nickel release either from the grip or the functional part: in 12% ($n = 72$) nickel was released from the grip area, and in 9.7% ($n = 58$) nickel was released from the functional part.

Nickel release by price group

On the basis of the individual price ranges of different types of tool (Table 2), all 516 tools were assigned to three terciles (low, medium and high price) (Fig. 2a).

Two hundred and sixty-three of 516 handheld tools were in the low-price category (tercile 1), 145 were in the intermediate-price category (tercile 2), and 108 were in the high-price category (tercile 3), as defined above (Fig. 2a).

In the analysis of nickel release from all tools in the three price terciles, a highly significant correlation ($p < 0.0001$) between price and nickel release was found, with less frequent nickel release from tools in tercile 3, and (with the exception of hammers, for which those in tercile 2 showed the highest frequency of nickel release) the highest frequency of nickel release from tools in tercile 1. The comparisons between tercile 1 and tercile 2 ($p = 0.0096$), and between tercile 1 and tercile 3, showed highly significant differences in nickel release (with higher release from tools in tercile 1), whereas the comparison between tercile 2 and tercile 3 did not show significant differences ($p = 0.0947$) (Fig. 2a).

In the analysis of subgroups of tools (Table 2) according to their function, a highly significant correlation between price and nickel release was found for lathe tools ($p = 0.0003$), wrenches ($p = 0.0017$), and hammers ($p = 0.0154$), whereas for spatulas ($p = 0.0544$) and all other tools ($p = 0.0682$ to $p = 0.8747$), the correlation did not reach the level of significance.

Nickel/cobalt release from handheld tools by country of origin

Of the tools and small hardware parts, 18.16% ($n = 109$) were labelled as 'made in Germany', and 1.83% ($n = 11$) as 'made in England', 'made in France', or 'Swiss-made'. The latter three were summarized as 'European countries'. For 80% ($n = 480$) of the tools and small hardware parts, no country of manufacture was given.

Among the 480 examined tools and small hardware parts lacking country of origin labelling, nickel release was detected from 136 objects (28.33%), and cobalt release was detected from only one object (0.2%).

Among the 109 tools and small hardware parts manufactured in Germany, nickel release was detected from 59 parts (54.13%), and cobalt release was detected from five parts (4.58%). Among the few tools made in European countries other than Germany, neither nickel nor cobalt release was detected (Fig. 2b). Tools 'made in Germany' released nickel significantly more frequently from parts or all parts than tools without labelling of country of origin (χ^2 value 32.3378, $p < 0.0001$).

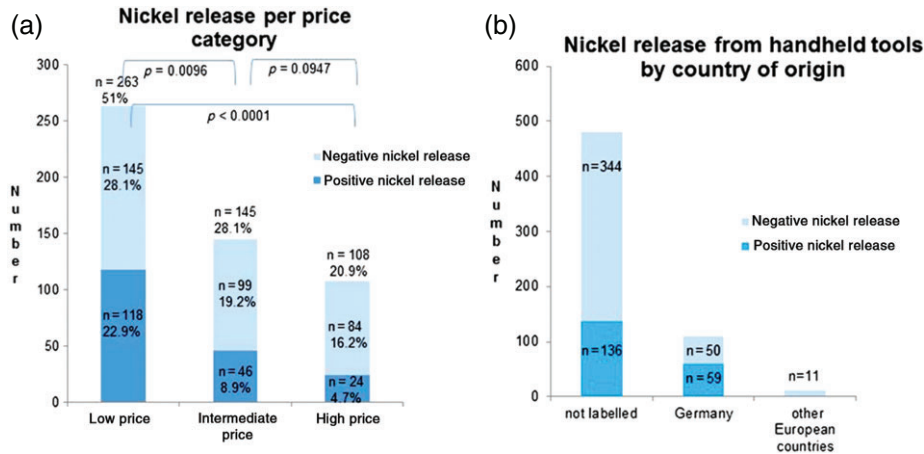


Fig. 2. (a) All tools (except for small hardware parts) were assigned to three price terciles based on the price range of the individual tool type (Table 2). Fifty-one percent ($n = 263$) of the examined tools belonged to the low-price tercile, 28.1% ($n = 145$) to the intermediate-price tercile, and 20.9% ($n = 108$) to the high-price tercile. Nickel release was found to be significantly more frequent in the low-price tercile than in the other two terciles. (b) With regard to the country of origin, unlabelled tools showed nickel release from less than one-third of the tools/parts. Tools 'made in Germany' showed nickel release in more than half of the examined tools, whereas tools made in other European countries showed no nickel release.

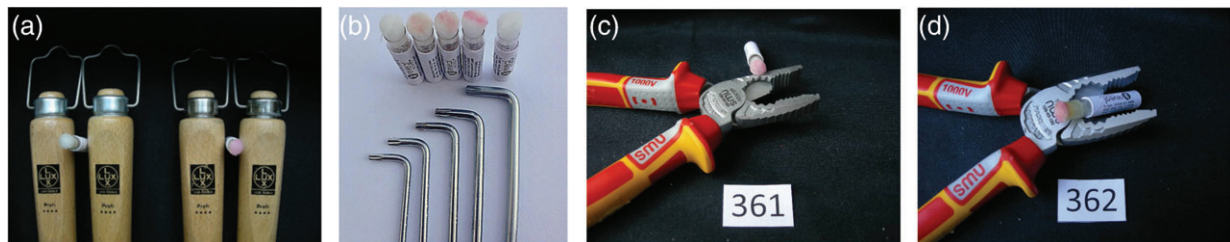


Fig. 3. (a) Identical tool set with (right) and without (left) nickel release from individual tools in the grip area (chisels). A colour difference of the metal is discernible. (b) Nickel release was found from three of five hex-wrenches (positions 2, 3, and 4) of one tool set. (c) Nickel release from the functional part. (d) Cobalt release from the functional part of pliers.

Evaluation of tool set homogeneity

A total of 38 tool sets were examined. Cobalt release was not detected for any of the sets. In 13 (34.2%) of the tool sets, nickel release varied, despite similar appearance of the tools: some of the tools from the kit showed nickel release, whereas others did not (Fig. 3a,b).

Discussion

Nickel ion release from objects intended to come into direct and prolonged contact with the skin has been regulated by the former EU Nickel Directive since 1994, and by the REACH Regulation (item 27 of Annex XVII) since 2009. Products that exceed the regulatory limits may no longer be sold in Germany (12). However, this law does not apply to all items that come into contact with bare skin. Many articles in daily use that are not included in the REACH Regulation [e.g. euro coins, coins of other

currencies (15, 17–19), and many keys (20)] release nickel. Other sources of possible nickel exposure can be found in mobile phones (21), hairpins (22), toys (16), kettles (23), and tools (24, 25). Nickel release above the legal threshold also occurs from costume jewellery, especially in Asian imports, despite the existing legal regulatory situation (26, 27). A lack of monitoring of compliance with the statutory limits (migration limit) has been pointed out, and a reduction in the migration limit has been suggested (11). Increased cobalt release from jewellery, on the other hand, has not been detected (28).

Between 2009 and 2013, 7126 hand eczema patients with occupational skin disease were patch tested with nickel(II) sulfate (5% in pet.) within the 52 dermatological departments in Germany, Austria and Switzerland contributing to the IVDK. Of these, 1108 patients (15.55%) had a positive test reaction to nickel. In only 8 cases (0.7%) tools were suspected as the source of nickel exposure. This

low number contrasts with our clinical experience gained in numerous expert assessments of occupational cases with hand eczema, in which nickel and cobalt release tests are routinely performed when contact sensitization to nickel or cobalt has been identified. Whereas patients are mostly aware of their nickel allergy, and are already avoiding skin contact with jeans buttons and costume jewellery, they are mostly not aware of their persistent nickel exposures resulting from contact with their individual handheld tools or keys, as detected by a positive DMG test result. Under-assessment and under-reporting of handheld tools as sources of persisting nickel exposure appear to be very likely.

Our study performed in Germany shows results very much in line with those of the first tool study performed in Sweden, in which 27% of 565 handheld tools with metal parts that come into contact with the skin were found to be DMG test-positive (29). Our study shows that, currently, nearly one-third of handheld tools purchased in Germany in 2013 release nickel. More than 50% of tools labelled 'made in Germany' release nickel, and 4% release cobalt. In comparison, nickel release was observed in only 28.3% of tools lacking country of origin labelling.

By many buyers, the label 'made in Germany' is currently regarded as a symbol of quality, reliability, and longevity (30); however, it does not indicate a low content of contact allergens. The term was originally introduced at the end of the 19th century in Great Britain for protection against cheap imitations, primarily knives and scissors, produced in Germany (31).

The 'made in' designation of origin in the EU is voluntary. Most consumers do not know that manufacturers are relatively free to refer to their products as 'made in Germany', even though they are made, to a large extent, abroad (30). Under current law, the country of origin refers only to the country in which an article was assembled. After numerous scandals regarding faulty goods, the European Parliament voted in October 2013 to pass a law

that obliges the manufacturer to specify the 'country of origin' as the one in which the major part of assembly has been performed (30). In consequence, many products actually labelled as 'made in Germany' would then have to be labelled as 'made in China' or 'made in North Africa' (29).

In the high-price category of tools, nickel release was significantly less frequent.

Approximately one-third of the tested tools from tool sets are not homogeneous with respect to nickel release. For consumers with a nickel allergy, an exemplary nickel release test on only a representative tool from the set is therefore not sufficient to rule out nickel release from the other tools in the kit. Therefore, an individual test for nickel/cobalt release is recommended.

In summary, in contrast to Denmark (25), an unexpectedly high proportion of handheld tools currently available in Germany released nickel. This has to be taken into account for the management of chronic hand eczema and for expert medical assessments of work-related hand eczema. In Germany, tools may still be sources of occupational sensitization, and may contribute to the elicitation and maintenance of hand eczema.

The risk of nickel sensitization from handheld tools does not seem to be comparable to the risk of nickel sensitization from jewellery and similar items (24). However, extending the scope of the REACH Regulation (item 27 of Annex XVII) on tools coming into direct and prolonged skin contact would be feasible. This concern has been repeatedly put forwards by different authors (11, 18, 21, 29, 32), and is supported by our recent data.

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