

Children's clothing fasteners as a potential source of exposure to releasable nickel ions

KATHERINE E. HEIM¹ AND BRUCE A. MCKEAN²

¹Nickel Institute, 55 University Ave, Suite 1801, Toronto, Ontario, M5J 2H7, Canada and

²Consultant to Nickel Institute

Background: Cutaneous nickel allergy in the very young is not well documented or characterized. A significant number of individuals are nickel sensitized by their mid-teenage years. Recent studies suggest that children may become sensitized to nickel at an early age.

Objectives: The purpose of this study was to investigate nickel release from children's clothing fasteners as one potential route of exposure of pre-school age children to nickel ions.

Patients/Methods: Fasteners from new and used children's clothing purchased in the USA were tested using the dimethylglyoxime (DMG) and EN1811 tests for nickel ion release.

Results: Of 173 fasteners tested, 10 (6%) tested positive using the DMG test for nickel release. EN 1811 standardized nickel release testing of these 10 items demonstrated that 70% (4% of all fasteners tested) released nickel in excess of the European Nickel Directive release limit (0.5 µg/cm²/week). Ten randomly selected DMG-negative fasteners were also EN 1811 tested, of which 30% of fasteners exceeded the European Nickel Directive release limit. Therefore, not less than 6% of the fasteners tested released excessive nickel.

Conclusion: This study concluded that clothing fasteners purchased in the USA could be a source of early childhood exposure to releasable nickel.

Key words: children; clothing; dermatitis; dimethylglyoxime; DMG; EN 1811; fasteners; metals; nickel; Nickel Directive; sensitization. © Blackwell Munksgaard, 2009.

Conflicts of interest: The authors have declared no conflicts.

Accepted for publication 27 September 2008

Nickel is a common cutaneous contact allergen, with the median nickel allergy prevalence in the general population being 8.6% (17% in women and 3% in men) in Western Europe and North America (1). The demonstrated significant prevalence of nickel sensitization in adolescent females has led to investigation of prevalence of nickel sensitization in young children, and even infants, for cutaneous nickel sensitization (2–13) in order to better understand at what age these individuals are being sensitized. Positive patch tests to nickel sulfate have been found in young children in some of these studies, with clinical prevalence rates being 24% in France (3), 34% in Austria (6), 10% in Germany (7), 18% in Spain (9), and 11% in Italy (10). The relevance of these patch

tests in children for nickel cutaneous sensitization is not clear because results of repeat testing are not consistent and the source of exposure is frequently not known (14–17). The question has been raised as to what the possible source of dermal nickel exposure could be for young children. The purpose of this study was to investigate clothing fasteners (e.g. snaps, rivets, buttons, etc.) as a possible source of exposure to releasable nickel that could result in cutaneous nickel sensitization.

Materials and Methods

A total of 173 fasteners (e.g. snaps, rivets, zippers, and buttons) from new (93 fasteners) and used (80 fasteners) clothing were collected. The clothing

was manufactured under 39 different product brand labels originating in 20 different countries. The sizes chosen were appropriate for ages between newborn and 5 years old with the period newborn to 3 years being most represented.

The new, unwashed clothing was purchased from four different commercial establishments in Durham, NC, USA. Each store represented a different price profile for goods: bargain (cheap) to high range (expensive). Every attempt was made to avoid duplicate items made by the same manufacturer, although sometimes the differences between pieces were minor.

Used, clean clothing was purchased at a clothing consignment sale (Kids Exchange, Raleigh, NC, USA) in order to capture clothing items manufactured over a period of time. In addition, fasteners on used clothing will have been exposed to strong detergents, sweat, and, in some cases, urine. This history would have some impact on any coatings that might have been used and would have possibly been worn thin or through during normal handling and use.

One fastener was cut out (with cloth attached) from each piece of clothing for testing so that they could be labelled and sorted more easily. For dimethylglyoxime (DMG) testing, the remaining cloth was not removed, whereas EN1811 testing required removal of the cloth and separation of the fastener into its components in some cases (e.g. snaps). Each fastener was labelled with a number. The clothing size, type of clothing (e.g. pyjamas, pants, shirt, etc.), brand (manufacturer), and country in which the product was made were recorded. Although the country of manufacture was noted, this was not considered to be of significant importance given the global operations of the industry and that the source of materials in the clothing is not necessarily the same as the country of manufacture of the clothing noted on the label.

The DMG test ('Allertest Ni'; Allerderm Laboratories, Phoenix, AZ, USA), using the standard protocol [equivalent to the standardized pre-test part of the PD CR 12471:2002 test protocol (18)], was used to test each fastener as a screening test due to the ease of use, little time involved for testing each item, and low cost. Briefly, one drop each of the DMG test solutions (1% DMG and 10% ammonium hydroxide) were applied to a cotton-tipped applicator (e.g. Q-tip), which was wiped on the relevant surface of the fastener for 15 seconds. Only surfaces that would potentially be in direct and prolonged contact with the skin were tested. The cotton swab was then observed for a pink colour as an indicator of significant amounts of releasable nickel ions. Canadian coins (5 cent

cupro-nickel and 25 cent nickel-plated steel) were used as positive controls and both tested positive.

The 10 clothing fasteners that tested positive in the DMG test plus one inconclusive result were sent to the Birmingham Assay Office (Birmingham, UK) for testing using the standardized EN 1811 test protocol (19). The flask volume was 5 ml, with a minimum surface area of the tested fasteners of 0.2 cm². Subsequently, an additional 10 fasteners were chosen at random from fasteners that tested negative in the DMG test and these were also tested using the EN 1811 test protocol. Where there were multiple parts to a fastener upon removal of the cloth, only the part that would be in contact with the skin was sent for testing. Briefly, for EN1811 testing test, items were immersed in synthetic sweat for 1 week. Surfaces of the fasteners that would not be in direct and prolonged contact with the skin were masked off (i.e. covered from exposure to synthetic sweat during immersion) using Lacomit™ Stopping Off Lacquer so that nickel release was measured from only surfaces that would potentially be in direct and prolonged contact with the skin. The amount of nickel ions released into the synthetic sweat was quantified using inductively coupled plasma optical emission spectrometry. The limit of detection was 0.012 µg Ni/cm²/week when the EN 1811 adjustment factor is applied (0.12 µg Ni/cm²/week without the adjustment factor). The resulting amount of nickel was then divided by the exposed surface area to determine the nickel release rate in micrograms of nickel per centimetre squared per week. The surface area of all fasteners was calculated manually using vernier callipers for taking measurements, with all callipers being calibrated annually and accurate to 0.01 mm. The nickel release rate was then multiplied by the 0.1 adjustment factor as part of the EN1811 standard method, which accounts for inaccuracy of the test.

Results

Of the 173 clothing fasteners tested with the DMG test, 10 were positive for nickel release and 1 was inconclusive. Representative positive DMG tests are shown in Fig. 1. None of the tested items was obviously coated with a lacquer. The nickel release rates from EN 1811 testing of these 11 items are shown in Table 1, along with the compliance of these items with the EU Nickel Directive. Seven fasteners (4% of the total 173 fasteners tested) were confirmed to have nickel release above the allowed limit according to the EU Nickel Directive (>0.5 µg Ni/cm²/week). Accuracy of the DMG results was evaluated based on

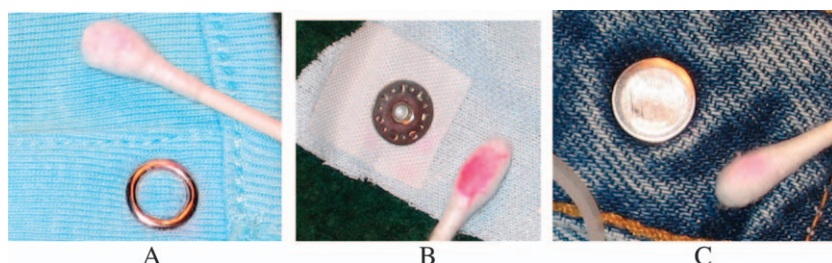


Fig. 1. Representative samples of dimethylglyoxime-positive test items, corresponding to items 1 (A), 2 (B), and 8 (C) in Table 1.

the EN 1811 results for the same item. False positives demonstrated a positive DMG result, but nickel release below the EU Nickel Directive limit and false negatives showed DMG-negative results with EN 1811 nickel release above the EU Nickel Directive limit. The one unclear result was not considered to be a false positive because the DMG result was uncertain and the EN 1811 test result was very low (below the EU Nickel Directive release rate limit). The EN 1811 results are the definitive results because the DMG test is known to produce false-positive and false-negative test results (20, 21), and the EN 1811 test is known to be more accurate and reliable than the DMG test in determining nickel release. The false-positive rate for the DMG test in this study was 30%.

The EN 1811 test results of 10 randomly chosen DMG-negative fasteners are shown in Table 2. Three of the 10 randomly selected DMG-negative fasteners were found to have nickel release above

the allowed limit according to the EU Nickel Directive ($>0.5 \mu\text{g Ni/cm}^2/\text{week}$), using the EN 1811 test. The false-negative rate for the DMG test in this batch of 10 random samples was 30%.

Discussion

The purpose of the study was to determine if children's clothing fasteners are a significant source of childhood exposure to nickel ions. The large number of the children's clothing fasteners was chosen to ensure reasonable statistical power. The variety of clothing selected was aimed at being representative of what children typically wear. Although the validity of the study in markets other than the USA cannot be assumed, the globalized nature of the industry means that the fasteners themselves, regardless of brand or country of manufacture, are likely to come predominantly from a few large common sources regardless of the brand or the intended market.

Table 1. EN 1811 results of fasteners testing positive or inconclusively using the DMG test

Item number	DMG test result	Nickel release rate ($\mu\text{g Ni/cm}^2/\text{week}$)	Adjusted* EN 1811 nickel release rate ($\mu\text{g Ni/cm}^2/\text{week}$)	European Nickel Directive compliance (yes or no) [†]
1	Positive	6.6	0.66	No
2	Positive	42	4.2	No
3	Positive	2.6	0.26	Yes
4	Unclear	0.12	$<0.012^{\ddagger}$	Yes
5	Positive	13	1.3	No
6	Positive	15	1.5	No
7	Positive	8.2	0.82	No
8	Positive	6.9	0.69	No
9	Positive	2.1	0.21	Yes
10	Positive	58	5.8	No
11	Positive	4.8	0.48	Yes

DMG, dimethylglyoxime.

*Values shown are measured nickel release rates multiplied by the 0.1 adjustment factor as part of the EN1811 test method. The measured values can be derived by dividing by 0.1.

[†]The European Nickel Directive (13, 14) specifies a nickel release rate limit of $0.5 \mu\text{g Ni/cm}^2/\text{week}$ (as measured by EN 1811) for items intended for direct and prolonged contact with the skin (excluding items worn in pierced body parts for which the release limit is $0.2 \mu\text{g Ni/cm}^2/\text{week}$).

[‡]Measured value was below the limit of detection of $0.12 \mu\text{g Ni/cm}^2$ without the adjustment factor and $0.012 \mu\text{g Ni/cm}^2$ with the adjustment factor.

Table 2. EN 1811 results of fasteners testing negative in the dimethylglyoxime test

Item number	Nickel release rate ($\mu\text{g Ni/cm}^2/\text{week}$)	Adjusted* EN 1811 nickel release rate ($\mu\text{g Ni/cm}^2/\text{week}$)	European Nickel Directive compliance (yes or no) [†]
12	<0.12	$<0.012^{\ddagger}$	Yes
13	<0.12	$<0.012^{\ddagger}$	Yes
14	120	12.0	No
15	11	1.1	No
16	<0.12	$<0.012^{\ddagger}$	Yes
17	<0.12	$<0.1^{\ddagger}$	Yes
18	24	2.4	No
19	<0.12	$<0.012^{\ddagger}$	Yes
20	<0.12	$<0.012^{\ddagger}$	Yes
21	<0.12	$<0.012^{\ddagger}$	Yes

*Values shown are measured nickel release rates multiplied by the 0.1 adjustment factor as part of the EN1811 test method. The measured values can be derived by dividing by 0.1.

[†]The European Nickel Directive specifies a nickel release rate limit of $0.5 \mu\text{g Ni/cm}^2/\text{week}$ (as measured by EN 1811) for items intended for direct and prolonged contact with the skin (excluding items worn in pierced body parts for which the release limit is $0.2 \mu\text{g Ni/cm}^2/\text{week}$).

[‡]Measured value was below the limit of detection of $0.12 \mu\text{g Ni/cm}^2$ without the adjustment factor and $0.012 \mu\text{g Ni/cm}^2$ with the adjustment factor.

Table 3. Summary of results and extrapolation to marketed fasteners

Total items DMG tested	Total items DMG and EN 1811 tested	Total items tested with DMG only	Observed false-positive rate*	Observed false-negative rate†	Minimum number confirmed non-compliant (% of total items tested)	Upper limit of possible non-compliant (% of total items tested)‡
173	21	152	30%	30%	10 (6%)	56 (32%)

DMG, dimethylglyoxime.

*False positive is defined in this study as demonstrating a positive DMG result but an adjusted nickel release rate below the EU Nickel Directive limit according to the current EN 1811 protocol.

†False negative is defined in this study as demonstrating a DMG-negative result with the adjusted EN 1811 nickel release rate above the EU Nickel Directive limit.

‡Using the false-negative rate of 30% of the items not tested by EN 1811 and the 10 EN 1811 tested items that released more nickel ions than the EU Nickel Directive limit, the maximum number of items that could release more nickel ions than the EU Nickel Directive limit would be 56 (32% of all the items tested).

The EU Nickel Directive (94/27/EC, amended 2004/98/EC) (22, 23) nickel release rate limit of $0.5 \mu\text{g Ni/cm}^2/\text{week}$ [as measured by the EN 1811 standard test (19)] for items intended for direct and prolonged contact with the skin (except piercing materials) was used as a benchmark in this study. Although the EU Nickel Directive specifies the inclusion of fasteners and rivets as examples of items that come into direct and prolonged contact with the skin, it is possible that some children's clothing manufacturer's do not consider that these fasteners are within the scope and intent of the Directive. This may lead to marketing of clothing that does not comply with the Directive. Direct and prolonged contact would be necessary to release a sufficient amount of nickel ions to cause nickel sensitization (induction) or nickel allergic contact dermatitis (elicitation) because the fasteners are made of metals or metal alloys that require corrosion to release metal ions. Therefore, the EU Nickel Directive nickel release rate limit was used to evaluate the risk of children's clothing fasteners for nickel sensitization and nickel allergic contact dermatitis. Because this release rate limit was derived from adults and is meant to protect all individuals from acquiring nickel sensitization and most nickel-sensitized individuals from experiencing nickel allergic contact dermatitis, it is not clear how this extrapolates to children. However, the threshold is not expected to be significantly different because the skin barrier and immune system are well developed in early childhood.

Due to ease of use and low cost, the DMG test was used as a screening test in this study to determine which fasteners may have a relatively high rate of nickel release. Previous studies have also used the DMG test to test nickel release from numerous items under the EU Nickel Directive (24, 25). The rate of false positives was expected to be high and was to be addressed by the testing

of the DMG-positive items using the EN1811 test. The rate of false negatives, however, was unexpected.

The high rate of false positives of the DMG test (26%) in the study by Manchada and Bayley (20) was similar to the rate of false positive in this study (30%). The report by Manchada and Bayley summarizes test results from four different laboratories, which tested identical samples of nickel metal and 10 homogeneous materials that covered a wide range of nickel release rates. Each material was tested using the full DMG test (PD CR 12471:2002) and EN 1811:1998 in order to determine the accuracy of the full DMG test. The rate of false positives in this study could be partially due to the fact that some of these items are likely to contain metals that confounded the DMG results (e.g. iron). Another contributing factor to the rate of false positives for the DMG is the EN 1811 adjustment factor of 0.1. Without this adjustment factor, there would not be any false positives. However, this adjustment factor is an essential part of the EN 1811 protocol and should be applied to the measured results. The EN 1811 adjustment factor of 0.1 exists to compensate for inter-laboratory variations and measuring inaccuracies. The European Committee of Standardization has been invited to review EN 1811 in particular regarding the adjustment factor and to prepare a revised standard without adjustment factor, or with a smaller adjustment factor, if appropriate. If this adjustment factor is revised, then the definition of false positive and negative may change for some of these results.

The high rate of false negatives (30%) was significantly higher than the 18% found by Manchada and Bayley (20) and 17% by Pönkä and Ekman (21). This could be due to a coating on the fasteners that was not penetrated by the brief DMG test but was not sufficient to protect the item from corrosion and subsequent nickel ion release in

the EN 1811 test. In addition, the random selection of fasteners could have coincidentally included more high nickel ion releasing fasteners than would be representative of all the DMG-negative fasteners. Another factor contributing to high false-negative rate could be that only 10 DMG-negative fasteners were tested, requiring only a few fasteners to test positive with the EN1811 test in order to result in an apparently high false-negative rate. Of particular interest are the false-negative results for item numbers 14 and 18 that had relatively high nickel release rates in the EN1811 test and negative DMG test results are particularly surprising. Ideally, these items would be retested using the DMG test to confirm the negative results, but the fasteners are not available for retesting. If one or both these values were not false negatives, it would significantly change the false-negative rate of the DMG test in this study. Regardless of whether the DMG test was positive or negative for these two items, the fact remains that a significant proportion of the fasteners in this study demonstrated nickel release values. The reported false-negative rate provides a wide range of possibilities for the potential exposure of children to a significant amount of nickel ions from clothing fasteners.

This study suggests that a minimum of 6% of the clothing fasteners are non-compliant with the EU Nickel Directive standard and a theoretical, although unlikely, maximum of 32% of the fasteners could be non-compliant (Table 3).

Conclusions

The objective of the study was to ascertain whether very young children in the USA may be receiving sufficient skin exposure to nickel ions from clothing fasteners to cause cutaneous nickel sensitization reactions (induction or elicitation). The authors have made the following conclusions:

- (1) Children's clothing fasteners can be a source of cutaneous nickel sensitization reactions in very young children. The minimum 6% of fasteners may appear modest but infants and young children grow out of clothes quickly. Thus, they are exposed to many different sets of clothes, each piece of which has, according to the study, at least a 6% chance of generating an unacceptable level of nickel ion release. Due to the high rate of false negatives using the DMG test, it is unclear what the magnitude of exposure to nickel ions, and therefore risk of cutaneous nickel sensitization reactions, is to children from clothing fasteners.

- (2) Due to the high rate of false positives and false negatives for the DMG test, its use as a screening tool is problematic. The EN 1811 protocol should be used as the definitive test to determine nickel ion release until the accuracy and reliability of the DMG test can be improved.

If the children's clothing fasteners used in this study are reasonably representative of the fasteners to which children are typically exposed, there appears to be an opportunity to reduce early childhood cutaneous exposure to nickel ions and prevent or reduce childhood cutaneous nickel sensitization reactions. The non-nickel-releasing fasteners, which were the majority of the fasteners, were indistinguishable in function and appearance from the nickel-releasing fasteners. Clearly, it is possible to manufacture fasteners without using nickel or nickel in readily releasable forms. The Nickel Institute will share the results of this study with the manufacturers ('brand owners') and retail stores that sold clothing with high nickel-releasing fasteners. In this context, the authors note that at least one clothing supplier is understood to require that attachments to clothing, such as fasteners, conform to the Nickel Directive (<http://www.levistrauss.com/Citizenship/ProductSourcing/OurApproach/CodeOfConduct.aspx>).

References

1. Thyssen J P, Linneberg A, Menné T, Johansen J D. The epidemiology of contact allergy in the general population – prevalence and main findings. *Contact Dermatitis* 2007; 57: 287–299.
2. Wantke F, Hemmer W, Focke M, Goltz M, Jarisch R. Age and sex distribution of contact dermatitis. *Contact Dermatitis* 1996; 34: 316–319.
3. Roul S, Ducombs G, Taieb A. Usefulness of the European standard series for patch testing in children. A 3 year single-centre study of 337 patients. *Contact Dermatitis* 1999; 41: 121–130.
4. Manzini B M, Ferdani G, Simonetti V, Donini M, Seidenari S. Contact sensitization in children. *Pediatr Dermatol* 1998; 15: 12–17.
5. Mortz C G, Lauritsen J M, Bindslev-Jensen C, Andersen K E. Nickel sensitization in adolescents and association with ear piercing, use of dental braces and hand eczema. The Odense Adolescence Cohort Study on Atopic Diseases and Dermatitis (TOACS). *Acta Derm Venereol* 2002; 82: 359–364.
6. Wohrl S, Hemmer W, Focke M, Götz M, Jarisch R. Patch testing in children, adults, and the elderly: influence of age and sex on sensitization patterns. *Pediatr Dermatol* 2003; 20: 119–123.
7. Heine G, Schnuch A, Uter W, Worm M. Frequency of contact allergy in German children and adolescents patch tested between 1995 and 2002: results from the Information Network of Departments of Dermatology and the German

- Contact Dermatitis Research Group. *Contact Dermatitis* 2004; 51: 111–117.
8. Lewis V J, Statham B N, Chowdhury M M. Allergic contact dermatitis in 191 consecutively patch tested children. *Contact Dermatitis* 2004; 51: 155–156.
 9. Fernandez Vozmediano J M, Armario Hita J C. Allergic contact dermatitis in children. *J Eur Acad Dermatol Venereol* 2005; 19: 42–46.
 10. Seidenari S, Giusti F, Pepe P, Mantovani L. Contact sensitization in 1094 children undergoing patch testing over a 7 year period. *Pediatr Dermatol* 2005; 22: 1–5.
 11. Beattie P E, Green C, Lowe G, Lewis-Jones M S. Which children should we patch test? *Clin Exp Dermatol* 2007; 32: 6–11.
 12. Clayton T H, Wilkinson S M, Rawcliffe C, Pollock B, Clark S M. Allergic contact dermatitis in children: should pattern of dermatitis determine referral? A retrospective study of 500 children tested between 1995 and 2004 in one UK centre. *Br J Dermatol* 2006; 154: 114–117.
 13. Goon A T, Goh C L. Patch testing of Singapore children and adolescents: our experience over 18 years. *Pediatr Dermatol* 2006; 23: 117–120.
 14. Dotterud L K, Falk E S. Contact allergy in relation to hand eczema and atopic diseases in north Norwegian schoolchildren. *Acta Paediatr* 1995; 84: 402–406.
 15. Simonetti V, Manzini B M, Seidenari S. Patch testing with nickel sulfate: comparison between 2 nickel sulfate preparations and 2 different test sites on the back. *Contact Dermatitis* 1998; 39: 187–191.
 16. Shah M, Lewis F M, Gawkrödger D J. Patch testing in children and adolescents: five years' experience and follow-up. *J Am Acad Dermatol* 1997; 37: 964–968.
 17. Pambor M, Krüger G, Winkler S. Results of patch testing in children. *Contact Dermatitis* 1992; 27: 326–328.
 18. European Committee for Standardization (CEN). Screening Tests for Nickel Release from Alloys and Coatings in Items that Come into Direct and Prolonged Contact with the Skin. *PD CR 12471, Brussels, CEN, 2002.*
 19. European Committee for Standardization (CEN). Reference Test Method for Release of Nickel from Products Intended to Come into Direct and Prolonged Contact with the Skin. *EN 1811, Brussels, CEN, 1998.*
 20. Manchada D, Bayley I. *NiPERA Project – Comparative Performance of Nickel Release Test Procedures: PD CR 12471:2002 and EN 1811:1998.* 2007. Report to NiPERA.
 21. Pönkä A, Ekman A. Insensitivity of the routine dimethylglyoxime test for detecting release of nickel from earrings. *Sci Total Environ* 1998; 224: 161–165.
 22. European Parliament and Council. Directive 94/27/EC. *Official Journal of the European Communities* 22-07-1994; No. L 188: 1–2.
 23. European Parliament and Commission. Directive 2004/96/EC. *Official Journal of the European Communities* 28-09-2004; No. L 301: 51–52.
 24. Lidén C, Johnsson S. Nickel on the Swedish market before the Nickel Directive. *Contact Dermatitis* 2001; 44: 7–12.
 25. Lidén C, Norberg K. Nickel on the Swedish market. Follow-up after implementation of the Nickel Directive. *Contact Dermatitis* 2005; 52: 29–35.
- Address:
Katherine E. Heim, PhD, DABT
113 Nuttree Way
Durham
NC 27713
USA
Tel: +919 403 0680
e-mail: kate.heim@verizon.net