

Nickel on the Swedish market before the Nickel Directive

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Nickel allergy is by far the most frequent contact allergy, affecting 10–15% of women in the general population, and causing dermatitis and hand eczema. The EU Nickel Directive, aimed at the prevention of nickel allergy, comes fully into force by July 2001. The Directive covers piercing materials, items in contact with the skin, and requirements on resistance to wear. We carried out a study of the prevalence on the market, before the Nickel Directive, of items that release nickel and of nickel in piercing posts. Nickel release, as shown by a positive dimethylglyoxime (DMG) test, was detected in 25% of 725 items intended for direct and prolonged contact with the skin. Of 15 posts intended for use during epithelialization after piercing, 60% contained more than 0.05% nickel. These products do not comply with the requirements of the EU Nickel Directive. It is suggested that experts in contact dermatitis participate in the prevention of nickel allergy by explaining its effects: the rôle of skin exposure and which parts of an item are in contact with the skin, and the crucial question of nickel release versus nickel content.

Key words: dimethylglyoxime test; nickel allergy; nickel content; Nickel Directive; nickel release; prevention. © Munksgaard, 2001.

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Contact allergy to nickel is by far the most frequent contact allergy in Europe, affecting 10–15% of females in the general population, and 15–25% of female dermatitis patients. A small % of males are also affected (1–6). Sensitization is often related to personal objects worn in prolonged contact with the skin. The type of object mainly responsible has varied with time, with fashion and with the use of different nickel-releasing materials in contact with the skin. Suspenders, jeans buttons, inexpensive jewellery, ear-piercing and earrings have been the items most frequently mentioned. Several sources of nickel exposure causing sensitization and elicitation are found among other personal items and in the home, leisure and occupational environments (7, 8). Dermatitis caused by nickel exposure was first described by Blaschko in 1889 among male platers exposed to nickel salts. 30–40% of nickel-sensitive persons develop hand eczema (4, 9). This is the most severe effect of nickel allergy and results in suffering, sick leave, change of jobs and large costs to the community.

During the past few decades, efforts have been made to prevent nickel allergy and nickel dermatitis. In 1989, Denmark decided on the limitation of nickel release from objects in contact with the

skin, and Sweden decided on the limitation of nickel content in ear-piercing materials (10, 11). Some other national limitations concerning nickel have been implemented by a few European countries. The broadest and most forceful regulation is the EU Nickel Directive. This covers piercing materials, a broad range of items in contact with the skin, and requirements on resistance to wear (12). The Nickel Directive was adopted by the European Parliament and Council in 1994. All member states should have adapted their legislation to the Directive by January 2000. Due to stepwise introduction, as from July 2000, importers and manufacturers may not place on the market products which fail to comply with the Directive, and 1 year later such products cannot be sold or made available to the final consumer. The Nickel Directive and the reference test methods for control of compliance with the Directive are presented in Table 1.

The present aim was to study the prevalence on the market, before the Nickel Directive, of items that release nickel and of nickel in piercing posts, so as to facilitate an estimate of the proportion of items not fulfilling future requirements. We also wished to create a basis for future evaluation of the effect of the Nickel Directive. The study was

Table 1. The EU Nickel Directive (12) and the reference test methods, European standards, for demonstration of conformity of products with the Directive (13–15)

Nickel may not be used ^{a)}	Reference test method
1. in post assemblies which are inserted into pierced ears and other pierced parts of the human body during epithelization of the wound caused by piercing, whether subsequently removed or not, unless such post assemblies are homogeneous and the concentration of nickel – expressed as mass of nickel to total mass – is less than 0.05%;	Body-piercing post assemblies – reference test method for determination of nickel content by flame atomic absorption spectrometry (EN 1810)
2. in products intended to come into direct and prolonged contact with the skin such as: earrings; necklaces, bracelets and chains, anklets, finger rings; rivet buttons, tighteners, rivets, zippers and metal marks when these are used in garments, if the rate of nickel release from the parts of these products coming into direct and prolonged contact with the skin is greater than 0.5 µg/cm ² /week;	Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin (EN 1811) ^{b)}
3. in products such as those listed in point 2 where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such products coming into direct and prolonged contact with the skin will not exceed 0.5 µg/cm ² /week for a period of at least two years of normal use of the product.	Method for the simulation of wear and corrosion for the detection of nickel release from coated items (EN 12472)

^{a)} Products which are the subject of points 1, 2 and 3, may not be placed on the market unless they conform to the requirements set out in those points⁷.

^{b)} Analysis of nickel released into artificial sweat. Screening tests based on the use of dimethylglyoxime (prEN 12471) are semi quantitative and do only give an indication of compliance with the requirements of the Directive.

conducted on behalf of the National Institute for Public Health.

Materials and Methods

The study was performed between April and July 1999. Our aim was to sample items that would be as representative as possible of the exposure of consumers of different age groups in the whole of Sweden.

Analysis of nickel release

Selection of shops and items. Head buyers and quality-control staff representing nationwide and dominant supplier organizations, or shops and chains selling jewellery, watches, spectacles, underwear and shoes, were invited to participate. All were in favour of participation and facilitated contact with suitable outlets in the Stockholm area. The managers of a few small shops were contacted by us directly. 21 shops or departments participated.

Items selected for the study were those covered by point 2 of the Nickel Directive and with metal parts coming into direct and prolonged contact with the skin in normal use. A total of 725 items were selected. They were sampled on visits to the shops and testing was carried out in the shops, behind the shopping area. Sewing accessories (metal buttons, zips, buckles, clasps, etc.) were the only items bought, and these were tested in our laboratory. 2 investigators simultaneously carried out the work together. The most frequently sold products, brands and models were selected, sometimes with the help of experienced shop assistants or managers.

Dimethylglyoxime test. Parts expected to come into direct and prolonged contact with the skin in normal use were subjected to the dimethylglyoxime (DMG) test for nickel release. More than 1 spot was often tested in each product.

The test solutions were DMG in ethanol 0.8% and ammonia 10%, prepared by the pharmacy, according to the pre-test of the prEN 12471 screening test for nickel release (16). 2 drops of DMG solution and 1 drop of ammonia were placed on a cotton-wool-tipped stick, which was rubbed for up to 15 s on the spot to be tested. The colour of the cotton was then read against a white background and the result was recorded and classified as negative (no colour), positive (pink colour), or doubtful (discoloration, not possible to classify).

Analysis of nickel content

Selection of items. 16 different piercing posts – jewellery intended for use during epithelization after piercing – were identified and bought from 1 piercing and tattoo studio, 1 youths' jewellery shop, 3 hairdressers and 1 producer. 15 posts made of metal were selected for analysis while 1 plastic item was not analysed. It was not possible to identify national organisations representing producers, retailers or the actual piercers.

Atomic absorption spectroscopy. Samples (2 mg) were taken from different parts of the items and were dissolved in appropriate acids (aqua regia and hydrofluoric acid respectively). The samples were diluted and analysed with atomic absorption spectroscopy for nickel content above or below 0.05%. Each part of every item was analysed separately. Sampling and analysis was carried out by SP

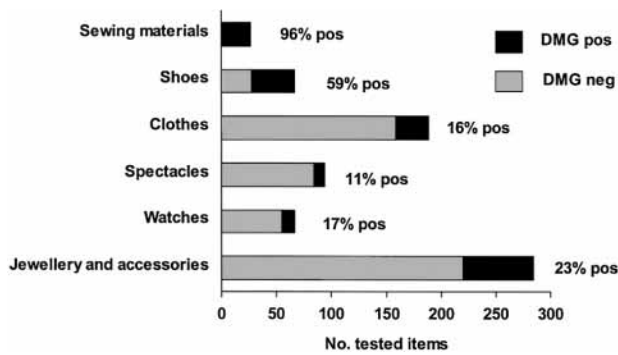


Fig. 1. Results of dimethylglyoxime (DMG) test on 725 items in 6 product types on Swedish market 1999.

Swedish National Testing and Research Institute, Borås, according to their standard procedure.

Results

Nickel release

The results of the DMG test for nickel release are shown in Fig. 1 and in Tables 2, 3.

Of the 725 items tested, 180 (25%) had a positive DMG test result. The proportion of DMG-test-positive items varied among product types, the highest being sewing materials (96%) and shoes (59%), followed by jewellery and accessories (23%), watches (17%), clothes (16%) and spectacles (11%). Among jewellery and accessories, hair-slides/headbands and belts were the types of item with the largest proportion of DMG-positive items (45% and 40% respectively).

A total of 1357 spots were tested on the 725 items. Of these spots, 227 tested positively, and 24 test results were doubtful, due to discoloration. Watches and spectacle frames were generally tested at several spots each, from 3–4 up to 9, as they often consisted of different metal parts joined together.

Table 3 displays roughly the distribution of DMG-positive items by intended user group – children, young people, ladies, gents and adults. 17–58% of the items in the different user groups were DMG-positive. Jewellery and accessories was the only product type specified for “young people”, although young people also used the other product types. The result for sewing materials (96%) is presented under “adults”, although these items are used by all groups.

Nickel content

The results of analysing the nickel content of 15 different metallic posts intended for use during epithelization after piercing are shown in Table 4.

Table 2. Detailed results of dimethylglyoxime (DMG) test on 725 items, 1357 different spots

Type of item (no. tested)	No. DMG-pos items	No. spots	
		tested	DMG pos
<i>jewellery and accessories</i>			
bracelet ($n=22$)	4	43	7
necklace ($n=63$)	6	144	12
necklace lock (separate) ($n=3$)	0	3	0
earring ($n=44$)	2	81	2
finger ring ($n=63$)	17	82	17
brooch ($n=6$)	0	6	0
hair slide/headband ($n=38$)	17	39	17
belt ($n=45$)	18	57	22
<i>watches</i>			
wristwatch ($n=46$)	6	228	8
finger ring watch ($n=9$)	2	29	3
wristwatch straps (separate) ($n=11$)	3	11	3
<i>spectacles</i>			
spectacles, prescribed ($n=56$)	6	155	11
ready-made spectacles ($n=8$)	2	19	5
sunglasses ($n=30$)	2	79	2
<i>clothes</i>			
trousers (except jeans) ($n=48$)	5	57	6
jeans ($n=25$)	1	40	1
shirt/blouse ($n=13$)	1	14	1
sweater/cardigan ($n=26$)	9	34	14
dress/skirt ($n=15$)	3	21	4
overall ($n=4$)	0	4	0
coat ($n=39$)	9	56	11
pyjamas ($n=8$)	1	8	1
bra ($n=11$)	2	22	2
<i>shoes</i>			
shoes ($n=25$)	16	29	17
sandals ($n=41$)	23	55	26
<i>sewing materials</i>			
button, zip, buckle, clasp ($n=26$)	25	41	35
all items ($n=725$)	180	1357	227

Samples were taken from 43 different parts of the items – jewellery part, ring, stud, stopper, and solder. The results of analysis by atomic absorption spectroscopy are presented as below or above 0.05% nickel, which is the limit value of Nickel Directive point 1 and the present regulation in Sweden. Of the 15 items tested, 9 (60%) had a nickel content above 0.05%. 5 items had a nickel content below the limit value, and according to denotations they were made of titanium or gold (nos. 1, 2, 13–15). 1 item (no. 4) was probably made of niobium and could not be analysed due to insolubility in the acids used. It is not known how many of the items were made of stainless steel, and only 1 (no. 3) was labelled KS 316 L stainless (KS probably standing for surgical steel). Few were labelled with any details concerning producer or composition.

Table 3. Results of dimethylglyoxime (DMG) test on 725 items; number of DMG-positive items by product type and intended users

Product type	No. DMG pos/no. tested items, per intended user group				
	children	young people	ladies	gents	adults ^{a)}
jewellery and accessories (<i>n</i> =284)	3/26	27/47	30/190	4/19	–
watches (<i>n</i> =66)	4/10	–	5/35	2/14	0/7
spectacles (<i>n</i> =94)	2/15	–	3/27	1/12	4/40
clothes (<i>n</i> =189)	10/83	–	16/63	4/24	1/18
shoes (<i>n</i> =66)	6/16	–	31/45	2/5	–
sewing materials (<i>n</i> =26)	–	–	–	–	25/26 ^{b)}
all items (<i>n</i> =725)	25/150	27/47	85/360	13/74	30/91

^{a)} Items intended for young people, ladies and gents, not specified.

^{b)} Intended for all groups.

Table 4. Results from analysis with atomic absorption spectrophotometry of nickel content in 15 metallic posts intended for use during epithelization after piercing; numbers of samples from different parts of each item; acid used for dissolving sample; nickel content below or above limit value 0.05%

Item	Supplier	Product denotation (appearance)	No. samples	Acid ^{a)}	Nickel content below (<) or above (>) 0.05%
1	piercing studio	pure titanium grade 1	3	hfa	<
2	piercing studio	18 K gold labret	3	aq. r.	<
3	piercing studio	KS 316 L stainless	2	aq. r.	>
4	piercing studio	niob blend	1	– ^{b)}	– ^{b)}
5	accessory shop for young people	caflon	3	aq. r.	>
6	accessory shop for young people	CS No 29DV00EX (golden)	3	aq. r.	>
7	accessory shop for young people	CS No 29DV00EX (silvery)	3	aq. r.	>
8	hairdresser A	(golden)	3	aq. r.	>
9	hairdresser B	(golden)	3	aq. r.	>
10	hairdresser C	(golden, blue stone)	3	aq. r.	>
11	hairdresser C	(silvery)	3	aq. r.	>
12	hairdresser C	(golden, red stone)	3	aq. r.	>
13	producer	gold plated 24 K plain	4	aq. r.	<
14	producer	golden titanium plain	3	hfa	<
15	producer	natural titanium plain	3	hfa	<

^{a)} Acid in which sample was dissolved for analysis. hfa=hydrofluoric acid; aq. r.=aqua regia.

^{b)} Sample (probably niobium) could not be dissolved in the acid and was not analysed.

Discussion

Nickel release, as shown by a positive DMG test, was detected in 25% of 725 items intended for direct and prolonged contact with the skin. Of 15 posts intended for use during epithelization after piercing, 60% contained more than 0.05% nickel. These products do not comply with the requirements of the EU Nickel Directive, and the piercing posts do not comply with present requirements concerning piercing materials in Sweden (11, 12).

The 725 DMG-tested items represent a sample made by us, as representative as possible of the national market, while the 15 piercing posts analysed included all types that we could identify. We do not know of any other study of this kind or this size, except for our study of nickel release from tools on the Swedish market (17). In that study, 27% of 565 hand-held tools released nickel from parts in contact with the skin, when tested with DMG. 34 items of jewellery were tested in the UK

by a more sensitive application of the DMG test (laboratory application of the prEN 12471) and 5 items were positive (18).

The present results concerning nickel release from tested objects are an underestimation in relation to the requirements of the Nickel Directive. The simple screening test using only DMG solution and ammonia is not as sensitive as the reference test method based on analysis of nickel release after 1 week in artificial sweat (EN 1811), or as the screening test methods including pre-treatment of the surface with artificial sweat and heat before DMG testing (prEN 12471). The DMG test does not affect many of the lacquers and coatings which may be worn during use and which may fail the reference test methods for nickel releases (EN 1811) and for wear and corrosion (EN 12472). 12 spectacle frames tested in the UK with different methods for nickel release all released nickel (19). Furthermore, lacquers were easily removed by gentle scraping. It was however not possible in the

present study to carry out such analyses on the large sample of products we wanted to investigate.

Our purpose was to create a baseline value for the nickel that was on the market before the Nickel Directive came into force, so as to permit future evaluation of its effect by repeating the study. It is probable that alterations in the nickel release and nickel content of items on the market can be recorded earlier and more easily than changes in the incidence or the prevalence of nickel allergy can be recorded by clinical and epidemiological studies. We show that the market had already reacted to the requirements of the Nickel Directive before it came into force. Many of the large in the fields affected have recently included nickel in their quality-control programme and are now doing their best to comply with the forthcoming regulation concerning nickel release. Had the study been carried out some years earlier, the proportion of DMG-positive items would presumably have been larger. In Denmark, there are already indications of a decrease in the sensitization rate to nickel among the youngest age groups, probably as an effect of the limitation of nickel release from items in contact with the skin (6).

There has been much lobbying by some parts of industry concerning the Nickel Directive and the reference test methods. This is part of the explanation for the long period between adoption of the Directive in 1994 and its coming into force in 2000. Firms producing spectacle frames, hair slides, watches and piercing posts may be mentioned particularly for their activity in trying to explain that their products are not a clinical problem, or that they are not, or should not, be covered by the Nickel Directive, or that the analytical methods are not relevant for their products. Firms participating in the CEN project developing the test methods, however, have been very constructive (20). In fact, metallic spectacle frames are well-known among nickel-sensitive patients, dermatologists and many opticians to cause dermatitis in nickel-sensitive persons. 12% of nickel-sensitive subjects in a patch-test study reported symptoms related to spectacle frames (20). This corresponds well with the study concerning nickel release from spectacle frames (19).

We foresee that the Nickel Directive will show great potential in the prevention of nickel allergy and dermatitis related to nickel exposure. To become an effective preventive force, however, experts in contact dermatitis need to participate by explaining the severe effects of nickel allergy, the rôle of skin exposure and which parts of an item are in contact with the skin, and the crucial question of nickel release versus nickel content. In Sweden, several authorities and organisations are

currently running joint information drives concerning nickel allergy and the Nickel Directive, targeting the general public, producers, retailers and environmental health officers.

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