

# Nickel on the Swedish market. Follow-up after implementation of the Nickel Directive

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The Nickel Directive aims at the prevention of sensitization and elicitation of nickel dermatitis. It limits nickel release from, and nickel content in, certain items. The Directive came into full force by July 2001. The aim of this study was to investigate the frequency on the market of items that release nickel and of nickel content in piercing posts, 2 years after coming into force of the Directive. Of special interest was to study changes compared to the situation in 1999, when a baseline study had been carried out. Nickel release from 786 items covered by the Nickel Directive was tested with the dimethylglyoxime (DMG) test, and nickel content in 18 piercing posts was analysed. Nickel release was shown from 8% of items intended for direct and prolonged contact with the skin, and 17% of the piercing posts contained too much nickel, a decrease compared to 1999. There has been significant adaptation to the requirements of the Nickel Directive. The DMG test is useful for screening for nickel release and for monitoring the market. Provided there is further adaptation to the requirements, the risk of sensitization and elicitation of nickel dermatitis will be significantly reduced.

**Key words:** dimethylglyoxime test; EU legislation; follow-up; nickel allergy; nickel content; Nickel Directive; nickel release; prevention. © Blackwell Munksgaard, 2005.

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Nickel is the most frequent cause of contact allergy in the industrialized world. In Europe, 10–15% of women and 2–5% of men in the general population are allergic to nickel, and the prevalence is even higher among dermatitis patients. 30–40% of nickel-sensitive people develop hand eczema that may be recurrent, chronic and severe, affect work ability and cause large costs (1, 2). This is the background to the EU Nickel Directive, which limits nickel in certain items so as to limit sensitization and elicitation of nickel dermatitis (Table 1) (3–5). The Nickel Directive was adopted in 1994, came into force stepwise from July 2000 and came into full force by July 2001. The Nickel Directive has 3 prongs, the 2nd of which limits nickel release from items in direct and prolonged contact with the skin. This is similar to a limitation adopted in 1989 in Denmark (6). The reference test methods for showing compliance with the Nickel Directive are 3 European Standards (Table 1) (7–9), while the reference test method according to the Danish regulation was the dimethylglyoxime (DMG) test. The European Commission has recently decided

on a revision of prong 1 of the Nickel Directive: The requirement concerning nickel content in piercing posts will be changed to a new requirement concerning nickel release (Table 1) (12).

Nickel is used in alloys, platings (such as nickel plating) and other applications in many types of items in contact with the skin. It is the ability of a material to release nickel ions on contact with the skin – and not the nickel content as such – which causes the risk of sensitization and contact dermatitis. German silver, copper–nickel and nickel–brass are examples of nickel-containing alloys with very high nickel release. White gold often contains nickel and the amount of nickel release varies. Nickel in stainless steels is generally firmly bound and not released in amounts considered to cause sensitization and dermatitis; but there are exceptions such as sulfur-rich stainless steels. Titanium, chromium, cobalt, iron, aluminium, copper, silver and gold are often used together with nickel in alloys, platings and other applications (13–15). Many types of objects, materials and activities have been associated with sensitization and elicitation of

Table 1. Summary of the EU Nickel Directive (3, 12) and test methods for demonstration of compliance with the Directive and a screening test (7–11)

| Nickel may not be used                                                                                                                                                                                                                                                                             | Test method – CEN document                                                                                                                                                                                                                                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. In post assemblies used during epithelialization after piercing unless they are homogenous and the nickel concentration is less than 0.05% <sup>a</sup>                                                                                                                                         | EN 1810: Nickel content analysed with atomic absorption spectrometry (reference test method)                                                                                                                                                                                                                                        |
| 2. In products intended to come into direct and prolonged contact with the skin such as earrings, necklaces, finger rings, wristwatches, buttons if nickel release from the parts coming into direct and prolonged contact with the skin is greater than 0.5 µg/cm <sup>2</sup> /week <sup>b</sup> | EN 1811: Objects to be tested are stored in artificial sweat at 30°C for 1 week. Nickel release into the solution is analysed (reference test method)<br>CR 12471: Screening test for nickel release based on the DMG test More sensitive and specific than the simple test by addition of artificial sweat, heat and dithiooxamide |
| 3. In products such as those listed under point 2 if they have a coating and if they do not fulfil the requirement under point 2 for a period 2 years of normal use                                                                                                                                | EN 12472: Objects are subjected to corrosion and wear by abrasive chips, simulating 2 years of normal use. Nickel release is then tested with EN 1811. (reference-test method) <sup>c</sup><br>ENV 14027: Method for wear of spectacle frames <sup>d</sup>                                                                          |

<sup>a</sup>New requirement from 2005: nickel release less than 0.2 µg/cm<sup>2</sup>/week from all items inserted into pierced parts of the body, not only during epithelialization after piercing (12).

<sup>b</sup>Spectacle frames, however, not listed as example do also have to comply with the Nickel Directive.

<sup>c</sup>EN 12472 is under revision by CEN.

<sup>d</sup>ENV 14027 is a temporary standard.

nickel dermatitis. Items often associated with nickel allergy are cheap jewellery, jeans buttons, watches, spectacle frames and, formerly, suspenders (1, 14, 16). Piercing has been much in focus during the past few decades (17–19). Exposure to nickel in some occupations contributes to nickel allergy and hand eczema (20).

In 1999, we studied the prevalence on the Swedish market of items that released nickel (as shown by the DMG test) and of nickel content in piercing posts (21). This was before the Nickel Directive came into force. The aim was to have a baseline value for future evaluation of the effect of the Nickel Directive. We found that 25% of the items tested were DMG-test positive and that 60% of the piercing posts contained more nickel than the limit value.

The present aim was to study the market in 2002/2003 in relation to the requirements of the EU Nickel Directive, almost 2 years after its full coming into force. Nickel release from items in direct and prolonged contact with the skin and the nickel content of items intended for use during epithelialization after piercing were studied. We also studied changes compared to the situation in 1999 before coming into force of the Nickel Directive.

### Materials and Methods

The study was performed between November 2002 and April 2003 in Stockholm, Sweden. The intention was to sample items that would be as representative as possible of exposure of consumers of different age groups in the whole of Sweden, such that the selection would allow for comparison with the results of the 1999 study (21).

### Selection of shops and items

Head buyers and quality-control staff representing nationwide suppliers or shops selling jewellery, watches, spectacles, clothes and shoes were invited to participate. Nearly all were in favour of participation and they provided contact with shops in the city of Stockholm. Market places and single small shops were contacted directly. A total of 21 shops selling jewellery, watches, spectacles, clothes, shoes, sewing materials and 3 market places, 5 piercing studios and 1 supplier of piercing posts (jewellery for use during epithelialization after piercing) participated. 13 of the shops belonged to nationwide and dominant supplier organizations. 15 had participated in the 1999 study. The intention was to select the same type of item, in equal proportions, as in 1999 and to cover the most frequently sold products, brands and models. The same type of shoe as in 1999 was not available due to seasonal variation in models. Compared to 1999, the selection was extended with items from market places. The piercing posts were selected to represent piercing in different body parts, different materials and different price levels.

A total of 786 items with metal parts coming into direct and prolonged contact with the skin were sampled by us at visits to the shops (Table 2). Most items were made available for testing in the shops, while 19 items from the market places and 26 sewing materials sold over-the-counter were bought. As the 18 piercing posts were to be destroyed by the analysis of nickel content, these items were bought at piercing studios or supplied by one producer.

Table 2. Product types and types of item tested with the dimethylglyoxime test in 2002/03 (n = 786)

| Product type              | Types of item                                                                                | Number of items tested |
|---------------------------|----------------------------------------------------------------------------------------------|------------------------|
| Jewellery and accessories | Belt, bracelet, braces, brooch, earring, finger ring, hair slide, necklace and piercing post | 272 <sup>a</sup>       |
| Watches                   | Wristwatch and wristwatch strap                                                              | 85                     |
| Spectacles                | Spectacles: prescribed, ready-made and sunglasses                                            | 153                    |
| Clothes                   | Coat, bra, pyjamas, shirt, skirt, sweater and trousers                                       | 158                    |
| Shoes                     | Boots, sandals and shoes                                                                     | 92                     |
| Sewing materials          | Button, buckle, clasp and zip (items sold over the counter)                                  | 26                     |

<sup>a</sup>19 items from market places and 18 piercing posts included.

### DMG test for nickel release

Parts expected to come into contact with the skin were subjected to the DMG test for nickel release. More than 1 spot was tested in many items. A total of 786 items and 1583 spots were tested. Solutions of DMG (1.0% in denatured ethanol) and ammonia (9.7% in water) (Apotekets nickel-test<sup>®</sup>, Apoteket AB, Stockholm, Sweden) were used. 2 drops of each solution were placed on a white cotton-wool-tipped stick, which was rubbed for up to 30 seconds on the spot to be tested. The colour of the cotton was then read against a white background. The result was recorded and classified as negative (no colour), positive (pink or red colour) or doubtful (discoloration, not possible to classify). In the case of discoloration, the surface was wiped with ethanol and the test repeated; the 2nd result was recorded.

Testing was carried out in the shops, often behind the shopping area. Items that had been bought by us were tested in our laboratory. 2 investigators carried out the work together, and one of the authors (KN) was always present.

### Analysis of nickel content

Piercing posts were analysed for nickel content above or below 0.05%, according to reference test method EN 1810 (Table 1) (7). The composition of the items was analysed with X-ray fluorescence semiquantitative analysis for classification of alloy type. Each post was then divided into smaller parts that were dissolved in appropriate acid according to EN 1810. The nickel content was analysed with flame atomic absorption spectrometry. The SP Swedish National Testing and Research Institute, Borås, Sweden, performed the analyses. All items had been DMG tested before the nickel content was analysed.

### Statistical analysis

Results from the baseline study in 1999 (21) and the present follow-up study in 2002/2003 were compared concerning DMG-test outcomes for

items in contact with the skin, and concerning nickel content (below or above 0.05%) in piercing posts. When comparing the positive DMG-test results between 1999 and 2002/2003, the doubtful DMG tests were treated in 2 alternative ways: counted as DMG positives or excluded from the comparison. The rationale was that the proportion of items with doubtful DMG-test result had increased, indicating increased use of alloys of different composition from those in the baseline study. The chi-square test was used and  $P < 0.005$  was considered statistically significant for the comparisons made.

## Results

### DMG test

The results of the DMG test for nickel release in 2002/2003 are shown in Table 3 and in Figs 1 and 2. The results from the baseline study in 1999 are included for comparison (21).

Of the 786 items tested in 2002/2003, 8% had a positive DMG-test result. The corresponding figure (25%) when 725 items were tested in 1999 was higher. The difference is statistically significant. The proportion of DMG-test-positive spots was 6% in 2002/2003 and higher, 17%, in 1999. The difference is statistically significant. The proportion of items with doubtful DMG-test result due to discoloration was 9% in 2002/2003 and lower, 3%, in 1999. The difference is also statistically significant.

The number and proportion of DMG-test-positive items varied among product types (Fig. 1). The largest proportion of DMG-test-positive items, in 2002/03, was found among sewing materials (42%), followed by jewellery and accessories (16%). The types of jewellery and accessory items with the highest rate of DMG-test positives were hair slides (57% DMG positive) and belts, braces, bracelets and necklaces (all more than 20% DMG positive). The proportion of DMG-test positives in the other product types (watches, spectacles, clothes and shoes) was 2–3%.

Table 3. Summary of results of dimethylglyoxime (DMG) test on items and on different spots in 1999 (21) and 2002/2003

| DMG-test result           | Number (percentage of all tested) |                          |                                        |
|---------------------------|-----------------------------------|--------------------------|----------------------------------------|
|                           | Baseline study, 1999              | Follow-up study, 2002/03 | Statistical analysis (Chi-square test) |
| All items tested          | <i>n</i> = 725                    | <i>n</i> = 786           | –                                      |
| Positive DMG test         | 180 (25)                          | 66 (8)                   | S                                      |
| Negative DMG test         | 524 (72)                          | 651 (83)                 | NT                                     |
| Doubtful DMG test         | 21 (3)                            | 69 (9)                   | S                                      |
| All spots tested on items | <i>n</i> = 1357                   | <i>n</i> = 1583          | –                                      |
| Positive DMG test         | 227 (17)                          | 101 (6)                  | S                                      |
| Negative DMG test         | 1106 (82)                         | 1400 (88)                | NT                                     |
| Doubtful DMG test         | 24 (2)                            | 82 (5)                   | S                                      |

The *P* values test the difference between results of 1999 and 2002/2003.

S = statistically significant; NT = not tested.

Compared to the results from the 1999 study, the decrease in DMG-test-positive items was statistically significant for product types jewellery and accessories, watches, spectacles and shoes, even when the doubtful results were counted as DMG-test positive (worst-case scenario). For clothes and sewing materials, the decrease in DMG positives was statistically significant only when the items with doubtful DMG-test result were excluded. The largest decrease was found among shoes (from 59% to 3% DMG-test positive) and sewing materials (from 96% to 42% DMG-test positive). The type of shoe tested in the 2 studies was, however, very different: largely sandals with buckles in 1999 and boots with zips in contact with skin in 2002/2003.

Figure 2 displays roughly the distribution of DMG-test-positive items by intended user group in 1999 and 2002/2003. Compared to the results in 1999, there has been a statistically significant decrease in DMG-test positives for young people

and women. Items intended for young people showed the largest decrease in DMG-test positives but also the highest proportion of such items. Sewing materials, although intended for all user groups, are presented under adults.

#### Nickel content in piercing posts

The nickel content and the main components were analysed in 18 piercing posts intended for use in ear, eyebrow, nose, tongue or navel during epithelialization after piercing. The results are summarized in Table 4. 3 of 18 (17%) contained more than 0.05% nickel, which is the limit value according to the Nickel Directive prong 1 (Table 1). In 1999, the corresponding result was 9 of 15 (60%). The difference is statistically significant. Analysis of the composition of the piercing posts showed that they were made of several alloys classified as titanium, steel or copper alloys. Those that were shown to contain more

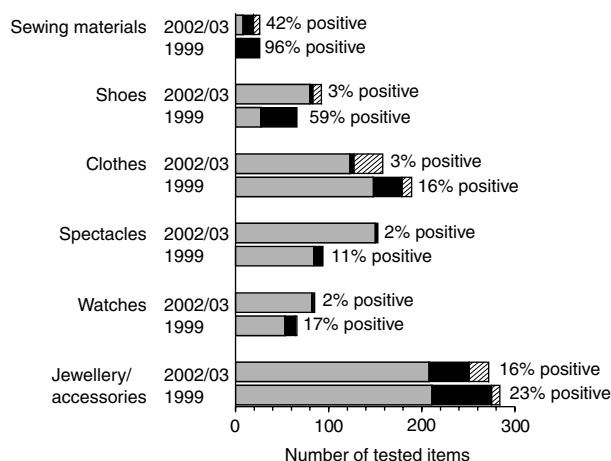


Fig. 1. Results of dimethylglyoxime (DMG) test on items on the Swedish market in 1999 (*n* = 725) and 2002/03 (*n* = 786) by product type. 25% of all tested items in 1999 were DMG-test positive as were 8% in 2002/03. ■ = DMG positive; ▨ = doubtful.

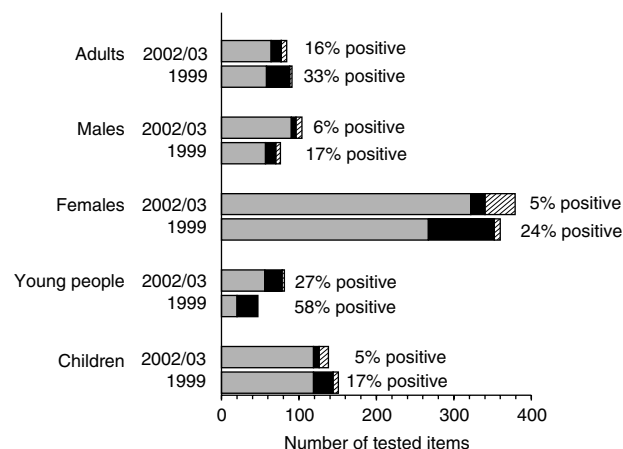


Fig. 2. Results of dimethylglyoxime (DMG) test on items on the Swedish market in 1999 (*n* = 725) and 2002/03 (*n* = 786) by intended user group. Sewing materials intended for all groups included in adults, 26 items in 1999 and 2002/03. ■ = DMG positive; ▨ = doubtful.

Table 4. Results from analysis of nickel content and main components in 18 metallic posts intended for use during epithelization after piercing. Description of the items. Analysis according to EN 1810 (7).

| Type of alloy <sup>a</sup> | Main element <sup>b</sup> | Nickel content (%) <sup>c</sup> | Product denotation <sup>d</sup> | Intended area of use <sup>e</sup> |
|----------------------------|---------------------------|---------------------------------|---------------------------------|-----------------------------------|
| Titanium                   | Ti                        | 0.02                            | Natural titanium (w)            | Ear                               |
|                            | Ti/Al/V                   | 0.02                            | Titanium (o)                    | Navel                             |
|                            | Ti/Al/V                   | 0.02                            | Titanium (o)                    | Navel                             |
|                            | Ti/Al/V/Si                | 0.03                            | Titanium (o)                    | Eyebrow                           |
|                            | Ti/Al/V/Si                | 0.03                            | Titanium (o)                    | Navel                             |
|                            | Ti/Al/V/Si                | 0.02                            | Titanium (o)                    | Tongue                            |
|                            | Ti/Al/V/Si                | 0.02                            | Titanium (o)                    | Eyebrow                           |
|                            | Ti/Au                     | 0.02                            | Golden titanium (w)             | Ear                               |
|                            | Ti/Au                     | 0.02                            | Golden titanium (w)             | Ear                               |
|                            | Ti/Fe/Al/V                | 0.02                            | Titanium (o)                    | Any area                          |
|                            | Ti/Fe/Al/V/Si             | 0.02                            | Titanium (o)                    | Nose                              |
|                            | Ti/V/Al                   | 0.02                            | Titanium (o)                    | Tongue and navel                  |
| Steel                      | Fe/Cr/Mn/Mo               | 0.04                            | Nickel negative (w)             | Any area                          |
|                            | Fe/Cr/Mn/Mo/Al            | 0.04                            | Nickel negative (w)             | Navel                             |
|                            | Fe/Cr/Ni/Mo               | 11.4                            | (-)                             | Navel                             |
|                            | Fe/Cr/Ni/Mo/Mn            | 11.7                            | (-)                             | Nose                              |
|                            | Fe/Cr/Ni/Si/Mo/Pb/Al      | 12.3                            | Titanium (o)                    | Navel                             |
| Copper                     | Cu/Zn/Sn/Si               | < 0.01                          | Nickel free (w)                 | Ear                               |

<sup>a</sup>Classification according to EN 1810.

<sup>b</sup>Elements in descending order of concentration according to analysis with X-ray fluorescence.

<sup>c</sup>According to analysis with atomic absorption spectrometry.

<sup>d</sup>Written on the package (w), orally by the retailer (o), no information available (-).

<sup>e</sup>According to the retailer or denotation on the package.

than 0.05% nickel had been classified as steel alloys. Denotation on the package concerning material was often lacking.

### Discussion

We have shown that a significant reduction of items with nickel release, as shown by the DMG test, occurred on the Swedish market from 1999 to 2002/2003. The present follow-up study, in 2002/2003, shows that 8% of 786 items in direct and prolonged contact with the skin released nickel and that 17% of 18 piercing posts contained too much nickel. In 1999, 25% of 725 items released nickel and 60% of 15 piercing posts contained too much nickel to comply with the Nickel Directive, which came into full force by July 2001. This indicates that producers and retailers have made serious efforts to adapt to the requirements.

The DMG test remains suitable for assessment of items on the market (21, 22). The test may serve as a guide to nickel release and it is quick, cheap and easy to perform. Some limitations of the DMG test, however, should be considered if it is used for screening for compliance with the Nickel Directive (Table 1). Discoloration may be caused by some materials and make the result difficult or impossible to assess. Platings or lacquers are not affected by the DMG test as much as by the reference test methods. The DMG-test

result is not quantitative and does not relate exactly to the Nickel Directive limit value for nickel release.

More items with doubtful DMG-test result were found in the present study than in 1999 (Table 3, Figs 1 and 2). This indicates a change in the selection of materials for production. The composition and nickel release of materials causing doubtful DMG-test results is to be studied, and the suitability of the more sensitive and specific CR 12471 screening test will be analysed.

Few spectacle frames were DMG-test positive. Note, however, that metallic spectacle frames are often plated or lacquered, and the base alloy might be a highly nickel-releasing alloy. While many spectacle frames previously had insufficient coatings in relation to the requirement of the Nickel Directive (23), the current situation is not known. Indications of considerable improvement were given by a survey of nickel release from more than 200 items, including spectacle frames, carried out in 2003. Nickel release was tested according to EN 1811 only (personal communication, Stephen Carter, Laboratory of Government Chemist, UK, September 2003). 2 large surveys of nickel release from spectacle frames, tested with the DMG test, do also indicate significant improvement. In the 1st study, 96% of 50 used spectacle frames and 25% of 373 new frames were DMG-test positive in areas in contact with the skin (24). In the 2nd study, 9% of 395 new frames were DMG-test positive in such areas (25).

Although our selection was limited, nearly all items from the market places were DMG-test positive (17 of 19 tested). We do not know what share of the market this area has, and it is presumably difficult to reach and affect retailers with information concerning the Nickel Directive. The authorities responsible could well consider these issues.

Knowledge, attitude and policy among producers and retailers, officials, and the general public may affect the impact of the legislation. We are planning to study this further. In Sweden, the National Chemicals Inspectorate and National Board of Health and Welfare, together with the local governments' environmental health authorities, are responsible for enforcing the Nickel Directive. In 2000, a joint project was carried out for nationwide information concerning the Nickel Directive. It was coordinated by the National Institute for Public Health and the National Chemicals Inspectorate and the National Board of Health and Welfare and the Swedish Consumer Agency, and other authorities and organizations participated. Information was designed and aimed at, for example, producers, retailers, consumers and local authorities. How far the project directly affected nickel on the market is not known. However, some local authorities in Sweden have carried out surveys of the market inspired by, and similar to, our 1999 study.

Some recent publications from Denmark indicate that the incidence of nickel allergy, and the association with hand eczema, has decreased as an effect of regulation limiting nickel release (18, 26, 27). The Danish experience is encouraging and emphasizes the importance of enforcing the Nickel Directive. Thus, it is of interest to assess the Directive's effectiveness. This may be done by monitoring the prevalence, incidence and severity of nickel allergy and dermatitis. Checking the market for compliance with the requirements is also important. This can be done easily by monitoring the prevalence of DMG-test-positive items, as we did. In other parts of the world, action is also being taken to prevent nickel allergy. China has adopted the same type of limitation as the EU Nickel Directive and the Chinese regulation will come into full force by September 2004 (GB 11887-2002). The Nickel Development Institute (NiDI) is encouraging governments and industry to act against nickel dermatitis and is currently active in Canada and Australia (personal communication, Bruce McKean, NiDI, August 2003).

We conclude that there has been a significant adaptation in Sweden to the requirements of the Nickel Directive and a reduction on the market of

items known to be major causes of sensitization to nickel. Some parties have adapted less well to the requirements, indicating ignorance of the issue. The DMG test is a useful tool for screening nickel release and may be used for monitoring the market. Given further improvement in adaptation to the Nickel Directive, the risk of sensitization and elicitation of nickel dermatitis will be significantly reduced.

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