

# A GUIDE TO THE DANGEROUS SUBSTANCES AND PREPARATIONS (NICKEL) (SAFETY) REGULATIONS 2005

## Introduction

The main objective of *The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2005* is to seek to prevent people becoming sensitised to nickel, which can lead to skin dermatitis. (see the Questions and Answers section for further information).

The Regulations come into force on 1<sup>st</sup> September 2005. Until that time, the *Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000*<sup>1</sup> continue to apply.

This Guide has been prepared in consultation with the Local Authorities Coordinators of Regulatory Services (LACORS) and is intended to help consumers and suppliers of products containing nickel understand how the Regulations affect them.

**The Guide seeks to provide practical advice with respect to the Regulations, which put into effect European Directives in the United Kingdom. The Guide does not carry any legal authority and does not replace the provisions of the Regulations. Only the Regulations, as interpreted by the Courts, have force of law.**

## Background to Legislation

To address the problem of nickel sensitisation, in June 1994 all Member States adopted Directive 94/27/EC<sup>2</sup> (the "Nickel" Directive). This Directive, the 12<sup>th</sup> Amendment to the "Marketing and Use" Directive, was implemented in the United Kingdom by means of the *Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000*.

In September 2004 Directive 2004/96/EC<sup>3</sup> was adopted. This Directive further amended the "Marketing and Use" Directive in respect of the provision relating to the use of nickel for piercing post assemblies. This amendment is implemented by the new Regulations. When they come into force on 1<sup>st</sup> September 2005 they will revoke the *Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000*.

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1 SI 2000/1668, available from HMSO or online at <http://www.opsi.gov.uk/si/si2000/20001668.htm>

2 European Parliament and Council Directive 94/27/EC of 30 June 1994 amending for the 12<sup>th</sup> time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. [OJ L188, 22.7.1994, p.1.]

3 Commission Directive 2004/96/EC of 27 September 2004 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of nickel for piercing post assemblies for the purpose of adapting its Annex 1 to technical progress. [OJ L301, 28.9.2004, p.51]

## Products covered

1. The Regulations prohibit the supply of any products intended to come into direct and prolonged contact with the skin, which contain nickel or a nickel compound, including:

- earrings
- necklaces, bracelets, chains, anklets and finger rings
- wrist-watch cases, watch straps and tighteners
- rivet buttons, tighteners, rivets and zippers and metal marks contained in or intended to be used in garments

unless the rate of nickel release (see below) from those parts of these products coming into direct and prolonged contact with the skin is 0.5 micrograms per square centimetre per week, or less.

2. With the exception of piercing post assemblies, products intended to come into direct and prolonged contact with the skin and that also have a *non-nickel coating* are prohibited for supply unless the rate of nickel release from those parts of these products coming into direct and prolonged contact with the skin is 0.5 micrograms per square centimetre per week, or less, when first supplied and thereafter for a period of two years of normal use.

3. Piercing post assemblies (see below), whether or not they have a non-nickel coating, are prohibited for supply unless their rate of nickel release is 0.2 micrograms per square centimetre per week, or less.

Products manufactured for export to countries outside the European Economic Area are not affected by these Regulations.

## Post Assembly

A post assembly is that part of the item designed and manufactured for insertion into the wound caused by piercing of the human body. The post assembly includes the piece that goes through the wound (a post or stud), plus any faces of the items that hold the piece in and against the wound (the rear of the stud or rear of the decorative part, and any accompanying butterfly).

## Nickel Release Rate

The Regulations prohibit the supply of *all* post assemblies (whether they are used during or after the period of healing of the wound caused by piercing) with a nickel release rate of 0.2 micrograms per square centimetre per week, or more<sup>4</sup>. This restriction applies to the ear-posts of

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<sup>4</sup> Until 1<sup>st</sup> September 2005, the nickel content of post assemblies intended for use during the period of epithelization (healing) of the wound caused by piercing must be less than 0.05% by mass. The British Standard Specification BE EN 1810:1998 is the reference test method for the measurement of nickel content.

ordinary earrings, whether or not they are plated with a non-nickel coating.

The Regulations also prohibit the supply of any other products that come into direct and prolonged contact with the skin that have a nickel release greater than 0.5 micrograms per square centimetre per week.

It is the supplier's responsibility to decide which parts of a piece will be in direct and prolonged contact with the skin. Advice can be sought from your Local Authority Trading Standards Department (in Great Britain) or the District Council (in Northern Ireland).

### **Testing**

It is advisable that an appropriately accredited test house carries out tests. Some organisations may prefer to use their own testing facilities; however, it is advisable that an accredited testing house periodically checks in-house measurements. The United Kingdom Accreditation Service can provide details of suitable testing houses – Tel: 020 8917 8400, website: [www.ukas.com](http://www.ukas.com).

### **Stock**

Within the European Community, only compliant products can be placed on the market. You can hold stock which does not comply – for sale outside the EU only – but it is essential to ensure that such stock is clearly identified.

### **Other Descriptions**

Descriptions such as 'nickel free', 'hypo-allergenic', 'nickel safe' etc are **not covered by the Regulations** and will continue to be covered by the Trade Descriptions Act 1968. If you wish to use such descriptions, it is your responsibility to ensure that they are accurate regarding your product and that you have sufficient evidence to substantiate their use. You should bear in mind that the obvious message to the consumer in using the term 'nickel free', for example, is that your product contains no nickel and therefore will not promote a nickel allergic reaction. Use of 'nickel free', under the Trade Descriptions Act, is only possible if nickel is present at concentrations that will not be material. What constitutes 'material' is a matter for the Courts to decide. However, evidence suggests that a nickel sensitive reaction is unlikely to occur at concentrations below 100 parts per million or 0.01%.

## **Test Methods used in the Regulations**

Regulation 4(1) provides that conformity with the requirements for nickel release rates under regulation 3 shall be demonstrated using the following specified standards: -

BS EN 1811:1999 is the reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin.

BS EN 12472:1999 is the reference test method for the simulation of wear and corrosion for the detection of nickel release from coated items.

This does not prevent manufacturers from testing their products using other test methods, but it does mean that their products must satisfy the requirements for the nickel release rates under regulation 3 when they are tested using the reference test methods BS EN 1811:1999 or BS EN 12472:1999.

## **Due Diligence**

Suppliers have a duty to ensure their products comply with the relevant legislation, which is known as showing 'due diligence'. If you wish to use the defence of due diligence, you will need to prove that you took all reasonable steps to avoid an offence being committed. What constitutes 'reasonable steps' depends on your circumstances, e.g. the size of your operation. In general, however, taking reasonable steps is likely to involve you setting up a control system that takes regard of the risks involved and covers all regulatory requirements. Such a system should be operated properly, kept under review and amended as necessary.

## **Further Information**

If you have any further queries, the Jewellery Distributors' Association and the British Jewellers' Association give advice to members free of charge. The Nickel Institute can provide advice on the release of nickel from nickel-containing alloys. Otherwise, you can contact your local Trading Standards office or the Department of Trade and Industry (DTI). DTI will make any amendments to the Regulations or supporting Test Standards as required.

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## Questions and Answers

### 1. Why is nickel a problem?

Nickel can cause allergic contact dermatitis (ACD). Signs of ACD range from dryness, chapping and inflammation of the skin to eczema and blisters.

Nickel sensitivity affects approximately 10% of women and 1% of men in western countries. It is not an inherited condition but is related to direct and prolonged skin contact with the substance. Nickel ACD was first noticed in industries where soluble forms of nickel came into contact with workers' skin, e.g. electroplating and battery manufacture.

Nickel sensitivity outside of occupational industries was first noticed in people who had skin contact with clothing buckles, zips and clasps that had been nickel-plated. ACD has increased with the use of nickel-plated jewellery and particularly with the practice of body-piercing.

### 2. How does nickel sensitisation happen?

When an item containing nickel comes into direct and prolonged contact with the skin, sweat can act on it to release nickel ions. Sensitisation can take between one and three weeks of such contact. The quantity of nickel ions required to induce it varies with individuals. Skin condition, other allergies, gender and age can all be factors. Some nickel-sensitised people may develop ACD with further exposure.

### 3. How long does nickel sensitisation last?

Nickel sensitisation lasts for life. However, some nickel-sensitised people display no symptoms (such as allergic skin rashes), either because they are minimally exposed or because relatively high amounts of nickel ions are required in them to cause ACD.

Short-term contact with nickel-releasing items such as keys, coins and tools is unlikely to lead to nickel allergy in non-sensitised people or cause ACD in those who are nickel sensitised.

### 4. How is nickel ACD treated?

Simply avoiding direct and prolonged exposure to nickel-releasing materials is often a sufficient remedy. ACD may also be treated with anti-inflammatory topical skin creams or ointments, e.g. cortisone-based skin moisturisers.

**5. Why has a maximum nickel content limit allowed in piercing post assemblies been replaced by a restriction on nickel release?**

It is not known precisely what concentration of nickel can cause sensitisation. Therefore a maximum nickel content was originally set at the lowest possible level to ensure protection from the risk of sensitisation. However, studies since have shown that certain types of stainless steel with a high nickel content do not elicit an allergic response in the majority of people who are already sensitised to nickel. When tests for migration (see Question 6) were performed on these stainless steels, very low levels of migrated nickel were detected, or could not be detected at all. Therefore, while the requirement of a maximum nickel content would remove any possibility of sensitisation, it was decided that this was not proportionate to the risk of sensitisation from products containing nickel that migrate little or none of the substance.

**6. What is migration and how is it measured?**

Migration is the measure of release of a substance from the surface of an object, usually into a liquid, over a period of time. For the purposes of testing under EN 1811, the media used is an artificial sweat solution which simulates human sweat. This standard requires a post assembly of known surface area to be immersed into a known volume of artificial sweat solution for a period of 1 week.

**7. Does the 0.2 micrograms per square centimetre per week limit only apply to piercing post assemblies used during the period of healing of the wound caused by piercing?**

No, the limit applies to all piercing post assemblies, whether they are used during or after the period of healing of the wound caused by piercing.

**8. Will the 0.2 and 0.5 micrograms per square centimetre per week limits prevent nickel sensitisation?**

These limits are confidently expected to reduce new incidences of nickel sensitisation, as experience in Denmark has shown.

**9. Will these limits prevent elicitation of nickel ACD in sensitised individuals?**

Unfortunately, even these extremely low levels of nickel release will not prevent all cases of elicitation of nickel allergy in people already sensitised to nickel.

**10. Is it permissible for piercing post assemblies to be plated with a non-nickel coating?**

Yes. Such post assemblies must comply with the 0.2 micrograms per square centimetre per week limit for nickel release as determined by the reference test method EN 1811

End

Consumer & Competition Policy Directorate  
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